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Effective Responses to the Clinical Challenges in Chronic Care Delivery: Findings from the Leuven Diabetes Project.

Geert GODERIS

Leuven, 2010

Doctoral thesis in Biomedical Sciences

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List of Abbreviations:

ASA= Acetyl Salicyclic Acid
ACE = Angiotensin Converting Enzyme
ADA = American Diabetes Association
AQIP = Advanced Quality Improvement Program
ARB = Angiotensin Receptor Blockers
BMI=Body Mass Index
BP= Blood Pressure
CCM = Chronic Care Model
CHD= Coronary Heart Disease
CI95% = 95% Confidence Interval
CV= Cardio Vascular
CVD=Cardiovascular Disease
DBP= Diastolic Blood Pressure
DSME = Diabetes Self-Management Education
DCCT= Diabetes Control and Complications Trial
GEE = Generalized Estimating Equations
GP=General Practitioner
IRN = Intego Registry Network
HDL-C = High Density Lipoprotein
HPLC=High-Performance Liquid Chromatography;
HT= Hypertension
IBM=Industrial Business Machines ©
IDCT=Interdisciplinary Diabetes Care Team
IDF= International Diabetes Federation
IKED=Initiatief voor Kwaliteitsbevordering en Epidemiologie bij Diabetes;
IOM = Institute Of Medicine
LDL-C=Low Density Lipoprotein Cholesterol
LDP=Leuven Diabetes Project
NIHDI = National Institute for Health and Disability Insurance
MNT= Medical Nutrition Therapy
OAD= Oral Andidiabetic Drug
QIP= Quality Improvement Program
P4P= Pay for Performance
P4Q= Pay for Quality
PAD=Peripheral Arterial Disease
PMS= Pluri Metabolic Syndrome
PP = 'Primary Prevention' (absence of history of CVD)
SP = 'Secondary Prevention' (presence of history of CVD)
SBP=Systolic Blood Pressure
T2DM= Type 2 Diabetes Mellitus
TG= Triglycerides
Tot-C = Total Cholesterol
TTM = Trans Theoretical Model of Change;
UKPDS= United Kingdom Diabetes Prospective Diabetes Study
UN = United Nations
UQIP = Usual Quality Improvement Program
µalb= Micro-albuminurie

General Introduction – setting the scene

"The most successful practices have an institutional priority for quality of care, involve all of the staff in their initiatives, redesign their delivery system, activate and educate their patients, and use electronic health record tools. (...) It is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of dedicated health care professionals working in an environment where quality care is a priority."

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Section 1: Chronic Diseases: the challenge for modern health care.

A chronic condition can be defined as a "*condition that requires ongoing adjustments by the affected person and interactions with the health care system*" (website of the Chronic Care Model, www.improvingchroniccare.org). Another, more comprehensive definition is put forward by the World Health Organisation: Chronic diseases are *"Diseases which have one or more of the following characteristics: they are permanent, leave residual disability, are caused by non reversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation or care" (WHO 2003).*

Chronic diseases are assumed to be the major cause of death and disability worldwide and they increasingly affect people. Non-communicable diseases such as cardiovascular diseases (CVD), diabetes, cancers and respiratory diseases account for 59% of the 57 million annual deaths and 46% of the global burden of disease. In developed countries, chronic diseases account for about 75% of total deaths (1; 2). Heart attacks and strokes kill about 12 million people every year. In addition, 3.9 million people die annually from hypertensive and other heart conditions (3). An estimated 285 million people are affected by diabetes, the majority by Type 2 Diabetes, representing 6.4% of the world's adult population. By 2030 the number of people with diabetes will be estimated at 438 million (4). In the United States, 133 million people, about 50% of the total population suffer from a chronic condition (5). Moreover, almost half of all people with chronic illness have multiple conditions (6). Since the prevalence of chronic diseases increases with age, increased longevity is a major contributor to the rising prevalence of chronic diseases and the aggregate costs of care for people with them (7). By 2050, the number of people in the European Union aged 65 and above is expected to grow by 70% and the number of people aged over 80 by 170%. Among the developed countries, Europe and Japan will experience the most pronounced ageing trends up to 2050 (8). In Flanders, 940.367 (about 20%) present with one or more chronic conditions (9), while the proportion of people aged 65 and above increased from 14% in 1990 to 18% in 2008 (10).

Chronic illnesses account for the expenditure of over 75% of direct health care costs in the United States, according to the Centres for Disease Control and Prevention of the U.S.(2) Healthcare expenditures on the single disease diabetes are expected to account for 11.6% of the total healthcare expenditure in the world in 2010 (376 billion USD) and expected to increase at 490 billion USD by 2030.(4) A Canadian study showed that about 60% of the costs related to chronic diseases are due to premature death, disability and complications (often inducing hospitalization) (1).

By some estimates, up to 70% of premature deaths and two-thirds of the cases of chronic disability are preventable (11). Prevention of chronic diseases and early and aggressive treatment probably can reduce a significant portion of the chronic disease burden (1;2;4). As such high quality treatment and follow-up of chronic diseases in an ageing population is one of the major challenges in future health care. Most health care systems are fundamentally designed to deliver ad hoc episodic care to patients with acute illness or acute manifestations of chronic illness. However, data for diseases such as diabetes, asthma and congestive heart failure clearly indicate that cost savings and quality improvements come from what happens over the long term to prevent acute episodes and complications from occurring (12-16). An increasing body of evidence indicates that quality improvement of chronic care requires a transformation of health care, from a system that is essentially reactive - responding mainly when a person is sick - to one that is proactive and focused on keeping a person as healthy as possible (17-21).

Section 2: Type 2 Diabetes Mellitus (T2DM).

Severe long-term complications

Type 2 Diabetes Mellitus (T2DM) is characterized by reduced insulin action (insulin resistance) and a relative insulin deficiency (22). Diabetes occurs when pancreatic β-cell hyper secretion of insulin fails to compensate for insulin resistance. Suboptimal treated Type 2 Diabetes Mellitus provokes major long-term complications with essentially a vascular origin, either macro-vascular (coronary artery disease, peripheral arterial disease, and stroke) or micro-vascular (diabetic nephropathy, neuropathy, and retinopathy). The large majority of T2DM presents with insulin resistance, which clusters with other Cardio Vascular (CV) risk factors (e.g. hypertension, dyslipidaemia, obesity, inflammation, hypercoagulability) and might in addition act as an independent CV risk factor. This cluster of risk factors is referred to as the plurimetabolic syndrome (PMS). Whereas chronic hyperglycemia leads to capillaries (microvascular) complications, PMS induces atherosclerosis and arterial (macrovascular) complications (23;24).

Macrovascular complications

Diabetes has been associated with coronary heart disease (CHD) since the late 19° century: it was recommended to test for glucose in the urine of patients with angina pectoris. However the occurrence of CVD in patients with diabetes was considered occasional until the end of the 20° century. Nowadays, we know that arterial complications cause around 65 to 80% of deaths in people with T2DM (25) compared with 30% in the general population. Diabetic patients have a two- to fourfold increased risk of CVD compared with non diabetic individuals (26;27). The relative risk of death from CHD is 1.5 to 2.5 times higher in diabetic men and more than 4 times higher in diabetic women compared with age-matched persons without diabetes. Several prospective studies in T2DM patients linked chronic hyperglycemia with increased CVD and all-cause mortality (28;29) independently of other cardiovascular risk factors (30). Haffner et al. observed that T2DM patients without coronary disease had a similar risk to contract a heart attack as non diabetic patients with known coronary disease (31). A recent Canadian population based study comparing 379 000 people with diabetes and over 9 million without the disease found that diabetic men and women with CVD were about 15 years younger than

those without diabetes in the same risk category (32). Moreover, T2DM abrogates sex differences in CV risk (33). The “European Guidelines on cardiovascular disease prevention in clinical practice” consider T2DM patients as subjects at high Cardiovascular risk (34).

Microvascular complications

Diabetic retinopathy may be the most common microvascular complication of diabetes. It is the leading cause of non traumatic blindness in the adult population (35). The risk of developing diabetic retinopathy depends on both the duration and the severity of hyperglycemia and presence of hypertension (36). Retinopathy may start as 7 years before the diagnosis (35).

Diabetic nephropathy is the leading cause of renal failure. It is defined by proteinuria > 500 mg in 24 hours in the setting of diabetes, but this is preceded by lower degrees of proteinuria, or “microalbuminuria.” Microalbuminuria is defined as albumin excretion of 30-299 mg/24 hours. Without intervention, diabetic patients with microalbuminuria typically progress to proteinuria and overt diabetic nephropathy. At the time of diagnosis, 7% of patients with Type 2 Diabetes Mellitus may have microalbuminuria (37).

Diabetic neuropathy is defined as “the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes” (38). There is no specific treatment of diabetic neuropathy. The primary goal of therapy is to control symptoms and prevent degeneration of neuropathy through improved glycemic control. Some studies have suggested that optimal glycemia control may improve symptoms of peripheral neuropathy (39).

Diabetic foot is in fact an umbrella term. Due to atherosclerosis of great and small vessel walls, diabetic neuropathy, a tendency to delayed wound healing and infection or gangrene of the foot is relatively common. It takes place in 15% of all patients with diabetes and precedes 84% of all lower leg amputations (40).

Evidence Based Treatment

In the Dutch NHG standard of 1993, one of the very few guidelines on the treatment of Type 2 Diabetes at that moment, only 2 objectives were put forward: "to control the blood sugar" and "to optimize the body weight" (41). Since 1993, a rapid evolution has taken place with regard to the scientific findings in the care for people with diabetes. Several landmark studies such as DCCT, UKPDS, Steno-2 and the Haffner study have determined the current approach of diabetes to a large extent. Indeed, clinical evidence suggests that aggressive, timely, and multi-factorial interventions (42) aimed at controlling risk factors such as high blood pressure (43), blood lipids (44;45), and glycemia (46;47) can reduce diabetes related complications in individuals with T2DM.

The results of these studies were translated into "evidence-based" guidelines. Most of the recommendations differ in a lot of details, but they match regarding the core recommendations on the treatment of Type 2 Diabetes:

- Treatment should be long-term and target-driven with an intensified intervention aimed at all validated targets.
- The cardiovascular preventive treatment of Type 2 Diabetes should start as soon as possible after the diagnosis.
- The treatment should be comprehensive ('global') including several drugs and education of patients on behaviour and lifestyle changes.
- Diabetes patients should receive lifelong treatment and follow-up. Diabetes has to be considered as a "chronic condition".
- Follow-up should include regular assessment of lifestyle habits (smoking status, exercise status and dietary habits), motivational status and treatment compliance and bio-clinical parameters (BMI, HbA1c, blood lipids and blood pressure) as well as regular screening on the occurrence of eventual complications (examination of the eyes, feet and screening on micro-albuminuria).

Actually, there is an international consensus about the key role of lifestyle (i.e. no smoking, regular physical activity, healthy diet, and weight control) not only in general management but also in CV risk prevention of T2DM patients.

The decreases in several bio-clinical parameters like HbA1c, blood pressure, cholesterol are associated with a reduction in CV risk in T2DM patients. Large CV risk reductions are observed with tapering of these parameters towards the normal range of the general population. Primary treatment targets can be set for HbA1c at 7%, for Blood Pressure at 130/80 mm Hg and for LDL-C at 100 mg/dl (70 mg/dl if history of CVD).

Metformin remains the first line drugs for reducing HbA1c, followed by sulfonylurea and then insulin. The new DPP4-inhibitors may be an alternative, especially in the frail elderly and exenatide can present an intermediary step between oral anti-diabetics and insulin therapy. However, the exact place of these new drugs still has to be determined.

Three types of drug-induced inhibitions have proved to be effective in CV risk reduction in T2DM patients. Inhibition of the angiotensin pathway (mainly through the *angiotensin-convertase enzyme* inhibition) by ACE-inhibitors or Angiotensin Receptor Blockers is generally considered as the first line treatment for diabetic patients with hypertension or microalbuminuria. Calcium channel blockers seem a reasonable choice for step up treatment, preferable to diuretics. Direct inhibition of AT-1 angiotensin receptors by sartans has not been shown to reduce CV risk more than ACE-inhibition does.

The inhibition of cholesterol metabolism (mainly through *HMG-CoA reductase* inhibition; statin therapy) is supported by overwhelming evidence.

Both the ADA standards and the European guidelines recommend a more general use of anti-platelet therapy despite the negative results of a recent meta-analysis (48). The ADA standards recommend the use of aspirin (75–162 mg/day) in all patients with a history of CVD and in patients > 40 years without a history of CVD and with at least one additional risk factor. The European guidelines on diabetes recommend that aspirin should be given for the same indications and in the same dosages to diabetic and non diabetic patients. A recent update of Diabetes UK guidelines recommends that people with diabetes who have established cardiovascular disease should be offered aspirin treatment and also recommends that people with diabetes but without known established cardiovascular disease should discuss their individual risk with their healthcare team (49).

Interestingly, the ADA standard is the only guideline that explicitly recommends a collaborative shared care approach in the management of Type 2 Diabetes patients. Further on, only the ADA standards and the European guideline recommend an individualized management plan.

Treatment targets according to three leading clinical guidelines:

	ADA 2009(50)	Europe 2007(51)	Prodigy UK 2007(52)
Smoking Abstinence	Yes	Yes	Yes
Healthy Diet	MNT	-	Healthier diet
Physical exercise			
Program	Aerobic/resistance	30-45min> 5days/w	>30 min >5days/w
Intensity	150 min/week	-	moderate exercise
Weight reduction			
indication	Overweight/obesity	Yes if obesity	Yes if overweight
Target	-5%, evtl. surgery	< 25 kg/m^3 or -10%	Aiming at 25 kg/m^2
HbA1c			
Target	<7 (in general) <<7 if possible Less stringent if necessary	<6.5 if possible	6.5 (population) 7.5 (intensive)
Glycemia, mg/dl			
Fasting	70-130	<108	-
Postprandial	<180	<135	-
Systolic BP, mmHg			
Target	<130	<130;125 if CVD+KD$^{\Psi}$	<140; <130 if KD, ED$^{\Phi}$, SP
Diastolic BP, mmHg			
Target	<80	<80; 75 CVD+KD	<80
Total-Chol, mg/dl			
Target	-	<175	<200
LDL-C, mg/dl			
Target	< 100 (PP) <70 (SP) -30-40%	<100 (PP) <70 (SP)	<115
HDL-C, mg/dl			
Target	> 40	>40 (men) >46 (women)	-
Triglycerides, mg/dl			
Target	< 150	> 150	-
Platelet inhibition			
ASA	Yes: in PP$^{¥}$ and SP$^{¥¥}$	Idem as non diabetics	Yes if CVD event
Clopidogrel	2° line	2° line	?
ACE-inhibition	1° line if HT$^{\|}$ or µalb	1° line if HT$^{\|}$ or µalb	1° line if HT
Cholesterol-inhibition			
Statin	Yes (algorithm)	Yes	Yes
Fibrate, ezetimibe,	-	sometimes	consider if TG>200
T2DM = High CV risk?	No	Yes	No
Global Treatment	Yes	Yes	Yes
Shared care (team)?	Yes	No	No
Management plan?	Yes	Yes	No
Education/DSME?	Yes	Yes	No

Archetype of chronic disease

Diabetes can be considered as the 'archetype' of a chronic condition because of several reasons. It is a highly prevalent disease (53) and uncontrolled diabetes will lead to serious complications in the long term (53). As such, the disease has a wide impact on the total human being. Usually there are only little or no short term complications. The disease deteriorates spontaneously over time and complications induce high costs (54). Evidence Based treatment has been described in well-documented and validated guidelines (55) and has proven to reduce both mortality and morbidity (42). Moreover well-designed Quality Improvement Programs in diabetes care are assumed to have an acceptable cost-effectiveness ratio (56-62). Evidence based diabetes care however is complex (63) and there is consensus in the literature that a quality gap exists (64). There is also a growing consensus that quality care for people with diabetes requires a coordinated input from different disciplines (20;65).

In this context, the diabetic epidemic creates new challenges for the health care systems which will have to introduce new approaches in order to cope with a disease of these dimensions. As such, changes in the approach of diabetes care in pilot projects and nation-wide programs are not only an aim in itself, they also could serve as a test case for the development of efficient care organization for other chronic conditions.

Section 3: The Chronic Care model: international model for quality of care.

A new model, the 'Chronic Care Model' (CCM) (66) has been developed as a response to the increasing challenges in chronic care delivery (Fig1). This model argues for important changes in the health care system, from a system that is essentially reactive - responding mainly when a person is sick - to one that is proactive, focused on keeping a person as healthy as possible.

The model has been developed to overcome four major deficiencies in the actual health care system. These deficiencies are:

- Lack of guideline based practice by practitioners conditioned for curing acute diseases
- Lack of multidisciplinary teamwork and care coordination
- Lack of pro-active, organized follow-up aimed at obtaining the therapeutic targets
- Patients inadequately prepared to contribute to the management of their illness

The model pictures three overlapping universes: 1. The entire community; 2. The health care system, including its payment structures; 3. The provider organization, whether an integrated delivery system, a small clinic or a loose network of physician practices and paramedical disciplines (67). Within these three universes, the CCM identifies the essential elements of a health care system that enables high quality chronic disease care. These elements are the health system, delivery system design, decision support, clinical information systems, self-management support for patients and the community.

(1) Improving the care for chronic diseases demands changes throughout the whole system organization. Key elements are leadership, adapted incentives, task arrangements and communication.

(2) Changes to the delivery system design include team changes with task delegation to ensure maximum quality of care including critical elements for which doctors may not have adequate training or time.

(3) Evidence Based treatment decisions need the availability of validated guidelines, which should also be discussed with patients. Other key elements are ongoing training, timely reminders and feedback to increase the availability of evidence based knowledge at the time that clinical decisions are made. Coaching of primary care providers by specialists, especially in the case of more complex patients is an important educational modality.

(4) Clinical information systems can assure access to key data on patients at the individual and population level, provide reminders for needed services to plan care, can identify groups of patients needing additional care and can monitor quality improvement efforts.

(5) Patients with a chronic disease occupy a central role in its management. Effective self-management support promotes a sense of responsibility by providing essential information, emotional support, and strategies for living with chronic illness. The CCM stresses the importance of a collaborative approach where providers and patients are working in a team, defining together the problems, setting priorities, establishing goals and treatment plans. There is no conclusive evidence about the effectiveness of self-management programs for the overall population of chronically ill, but there is conclusive evidence in some subgroups of people with diabetes (68).

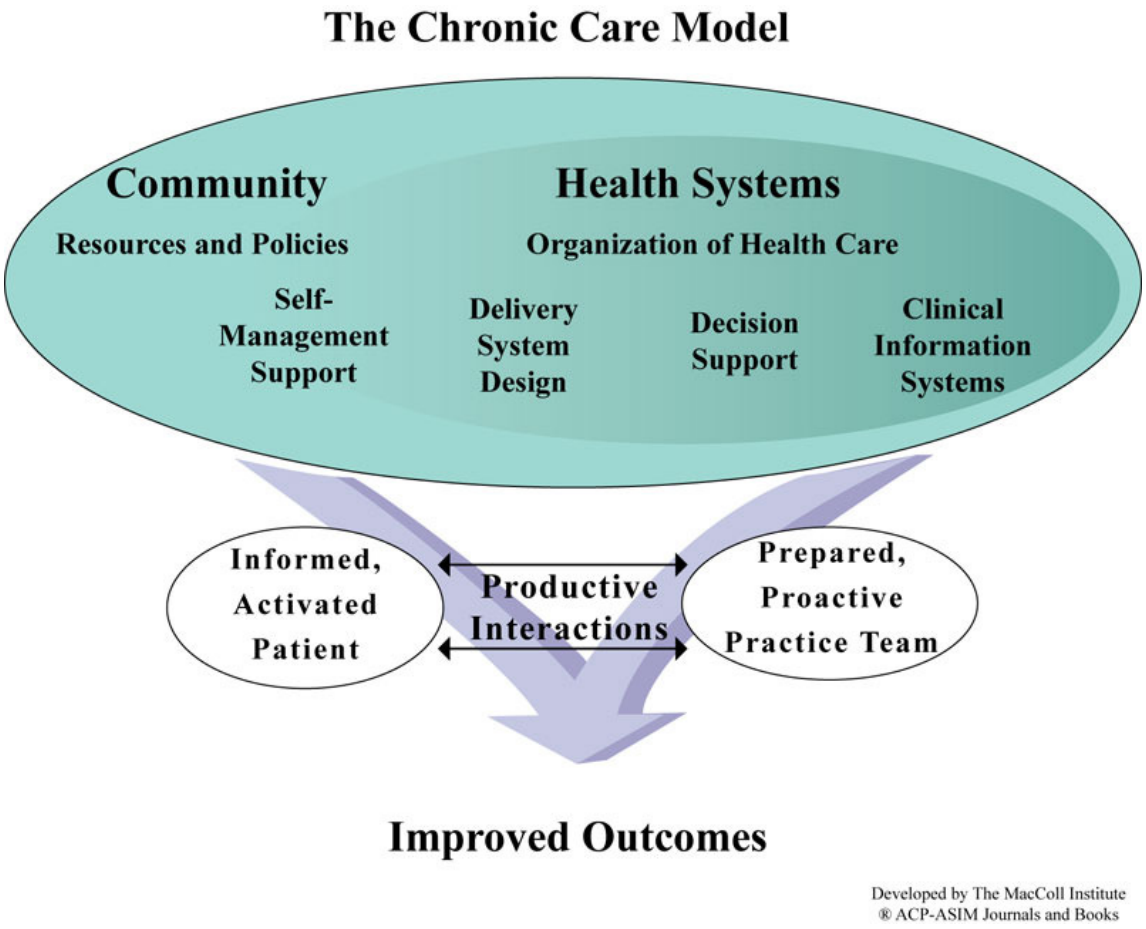
(6) Community programs can support a health system's care for chronically ill patients.

BOX 1.

Quality of care can be defined as *"the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (69).* [Institute of Medicine - Lohr 1990] As such, quality of care is closely linked to evidence based medicine.

Evidence based health care *"takes place when decisions that affect the care of patients are taken with due weight accorded to all valid, relevant information (70)."* Evidence based health care deals with policy decisions on groups of patients at the population level and can be considered as the result of the combined effect of three factors: 1. the disposable evidence; 2. the prevailing values, attitudes and structures; 3. the available financial resources.

Figure 1: The Chronic Care Model (reproduced from Wagner. Et al.)



Section 4: Implementation science and change management: the missing link.

While the Chronic Care Model gives a very comprehensive overview of the necessary system changes and quality improvement interventions to assure optimal quality of care, it does not explain how to implement it and it does not take into account the facilitation methods to assure a *successful change* from the 'old system' to the 'new system'. Many barriers at all levels can hamper the implementation of the above defined quality improvement interventions. Overcoming those barriers demands specific methods and interventions that are not described in the Chronic Care Model. These methods and interventions are the subject of research in the so called "Implementation science". Implementation can be defined as « *the introduction of an innovation in daily routine practice; this requires effective communication strategies and the removal of obstacles to change through the use of educational and policy techniques which are effective in practice*» (71). The medical "innovations" are generally outlined in practice guidelines. Several conceptual frameworks on guideline implementation and quality improvement have been described in the literature. We focus on the "Implementation Model" (Grol et al.) (71) as a methodological framework for implementation strategies and change management. The authors confirm that *"for most changes in health care, a range of factors interact at different levels (patients, professionals, interactions among professionals in teams, the organizational context, and the economic and political context) to determine whether and to what extent change is achieved". S*uccess or failure of guideline implementation depends on a complete range factors that can be subdivided in 6 groups:

- Characteristics of the **guideline**: clarity, feasibility, scientific value
- Characteristics of the **health care providers:** knowledge, skills, attitudes, belief, standards, values, personality traits
- Characteristics of the **patient:** knowledge, behaviour, compliance, needs
- Characteristics of the **social context**: attitude of the colleagues, cultural and social influences, opinion leaders
- Characteristics of the **economic, administrative and organizational context**
- Characteristics of the **methods and strategies of dissemination and implementation**: choice of the method, intensity and prince, source and executants.

The authors stress the importance to acquire full knowledge of the multiple theories that are involved in implementation science and to apply these theories to the 'local' social, organizational, political and financial context: "*For any innovation to be implemented successfully, it is necessary to identify the potential interacting determining factors*. *In turn, these factors can be described by and derived from different theories that need to be tested for their single or combined influence on change. This approach requires understanding the range of available theories and their applicability to health care" (72).*

Section 5: The effectiveness of Quality Improvement Interventions.

Quality improvement interventions have increasingly been tested on their effectiveness. In the Cochrane Library, the 'Effective Practice Organization of Care' (EPOC) dedicates an entire topic of systematic reviews and meta-analyses and divided QI interventions in 11 categories (box 2). However, this taxonomy does not include all possible interventions (box 3). In 2009, the Cochrane Collaboration evaluated the number and quality of reviews of change interventions from 1966 to 2008 (73). 193 reviews were identified in over 100 journals, including 32 Cochrane reviews; most of them published the last 15 years. Corresponding authors of SRs were mostly from USA, UK and Canada. Educational meetings, educational materials, reminders, audit and feedback and multifaceted strategies were the most commonly evaluated interventions. In order to give an overview of the most interesting issues about quality improvement, related to the topic of this thesis, we conducted a narrative review searching for systematic reviews on quality improvement interventions in diabetes care, on the implementation of the Chronic Care Model, on Pay for Performance interventions and public reporting. We searched in the Cochrane Library, Medline, Embase and the Centre for Review Dissemination (CRD) as well as for public reports of the Institute of Medicine (IOM, US), the Agency for Healthcare Research and Quality (AHRQ, US), the National Health Service (NHS, UK) and the Belgian Health Care Knowledge Centre (KCE).

Systematic Reviews on Quality Improvement

Single interventions at the professional level

Shojania et al (2006) assessed the impact on glycemic control of the 11 EPOC QI strategies in adults with Type 2 Diabetes and found that most QI strategies produced small to modest improvements in glycemic control (reduction of Hba1c values by a mean of 0.42% (95% confidence interval [CI], 0.29%-0.54%) over a median of 13 months of follow-up. Trials with mean baseline HbA1c values of 8.0% or greater reported significantly larger effects (0.54% vs. 0.20%, P = .005). Team changes and case management showed more robust improvements, especially for interventions in which case managers could adjust medications without awaiting physician approval.

The review may have been biased by difficulty in classifying complex interventions, insufficient numbers of studies, and publication bias.

Guldberg et al. (2009) reviewed the effect of feedback to general practitioners on quality of care for people with Type 2 Diabetes and found that feedback improved the care for patients with T2DM, particularly process outcomes. Clinical outcomes like lowering of blood pressure, Hba1c and cholesterol levels were seen in only few studies (74). These results are in line with a Cochrane Review that evaluated more in general (not disease specific) the effects on professional practice and health care outcomes (75). Garg et al. (2005) assessed the effects of computerized-clinical decision support systems (CDSSs) on practitioner performance and patient outcomes. The authors concluded that many CDSSs improve practitioner performance, whereas the effects on patient outcomes were understudied and inconsistent when examined (76). More recently (2009), Shojania et al. evaluated the effects of on-screen, point of care computer reminders on processes and outcomes of care and found that these QI interventions generally achieve small to modest improvements in provider behaviour (77).

Doumit et al. (2007) found that the use of local opinion leaders can successfully promote evidence-based practice (78). Forsetlund et al. (2009) found that educational meetings alone or combined with other interventions, can improve professional practice and healthcare outcomes for the patients. The effect is most likely to be small and similar to other types of continuing medical education, such as audit and feedback, and educational outreach visits. Strategies to increase attendance at educational meetings may increase the effectiveness of educational meetings. Educational meetings alone are not likely to be effective for changing complex behaviours (79).

Single interventions at the patient level

A recent meta-analysis (2009) evaluated the effectiveness of individual patient education on metabolic control, diabetes knowledge and psychosocial outcomes (80) and found a benefit of individual education on glycemic control when compared with usual care in a subgroup of those patients with a baseline HbA1c greater than 8% [-0.3% (95% CI -0.5 to -0.1, P = 0.007)]. However, overall there did not appear to be a significant difference between individual education and usual care. In studies

comparing group and individual education, there was an equal impact on HbA1c. Additionally, it would seem that education delivered by a team of educators, with some degree of reinforcement of that education made at additional points of contact, may provide the best opportunity for improvements in patient outcomes (81). A Cochrane review assessed the effectiveness of group-based training for self-management strategies in people with Type 2 Diabetes and found this approach effective by improving fasting blood glucose levels, glycated hemoglobin and diabetes knowledge and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication (82). Another Cochrane review assessed the effectiveness of lay-led self-management programmes for people with chronic conditions and found that those programmes may lead to small, short-term improvements in participants' self-efficacy, self-rated health, cognitive symptom management, and frequency of aerobic exercise. There is currently no evidence to suggest that such programmes improve psychological health, symptoms or health-related quality of life, or that they significantly alter healthcare use (83).

Balas et al. (2004) assessed the effects of computerized information interventions in diabetes care at the patient level; more precisely computerized prompting of diabetes care, utilization of home glucose records in computer-assisted insulin dose adjustment, and computer-assisted diabetes patient education. The authors concluded that these interventions could improve measures of diabetic care. The results however were not consistent among the studies or outcomes (84).

Multifaceted and/or multilevel interventions

The Chronic Care Model

Reviews that evaluate the effectiveness of the Chronic Care Model are rather consistent in their conclusions:

Tsai et al. (2005) found that interventions that contain at least 1 CCM element for asthma, congestive heart failure (CHF), depression, and diabetes improved clinical outcomes and processes of care (85). Coleman et al. (2009) examined the evidence of the CCM's effectiveness by reviewing articles published since 2000 that used one of five key CCM papers as a reference. They concluded that accumulated evidence supports the CCM as an integrated framework to guide practice redesign and that

redesigning care using the CCM leads to improved patient care and better health outcomes (86).

The NHS reviewed in 2005 560 systematic reviews, randomized trials and other studies (87). They concluded that initiatives to improve the care of people with long-term conditions can enhance satisfaction with care, quality of life, and in some cases, use of health services. They found sufficient evidence to support following initiatives:

- Broad chronic care management models
- Integrated community and hospital care
- Greater reliance on primary care
- Identifying people at greatest risk of complications and hospitalization
- Involving people with long-term conditions in decision-making
- Providing accessible structured information for people with long-term conditions and their families
- Self-management education
- Self-monitoring and referral systems
- Electronic monitoring and telemonitoring
- Using nurse-led strategies, where appropriate

A Systematic review of the Chronic Care Model in chronic obstructive pulmonary disease prevention and management found that patients with chronic obstructive pulmonary disease who received
interventions with 2 or more CCM components had lower rates of hospitalizations and emergency/unscheduled visits and a shorter length of stay compared with control groups (88). A meta-analysis on the effectiveness of Chronic Care Model-oriented interventions to improve quality of diabetes care found 69 studies (43 randomized controlled trials and 26 controlled before-after studies) with a mean reduction of 0.46% (95% CI 0.38, 0.54) in HbA1c, mean reduction of 2.2 (95% CI 0.9, 3.5) mmHg in systolic blood pressure, mean reduction of 1.3 (95% CI 0.6, 2.1) mmHg in diastolic blood pressure and mean reduction of 9 (95% CI 2, 16) mg/dl in total cholesterol. For specific CCM components, interventions that addressed delivery system design reported the largest improvements in patient outcomes, followed by those employing a self-management support component. Interventions involving decision support or clinical information systems reported relatively smaller effect

sizes.

The authors concluded that interventions featuring CCM components for diabetes care produced small-to-moderate improvements in a range of patient intermediate outcomes (89).

Quality Improvement collaborative:

A systematic review on quality improvement collaborative concluded that the effects of quality improvement collaborative on quality of care are uncertain; they may at best have only a moderate effect on outcomes (90).

Shared Care and interdisciplinary collaboration:

Smith et al. (2007) evaluated the effectiveness of shared care across the interface between primary and specialty care in chronic disease management. The authors found insufficient evidence to demonstrate significant benefits from shared care apart from improved prescribing but admit that methodological shortcomings of the studies may have biased the review (91). A Dutch review evaluated the effect of sharing and allocation of diabetes care concluded that sharing and allocation of diabetes care leads to significant reduction in HbA1c and improves the process of care (92).

A recent meta-analysis evaluating the effectiveness of interactive communication between collaborating primary care physicians and specialists on outcomes relating to patients in ambulatory diabetes care found that interactive communication resulted in moderate, statistically significant improvements in HbA1c (-0.64, 95% CI -0.93 to -0.34)(93).

Tailored interventions:

In a systematic review on tailored interventions, Shaw et al. (2005) found that interventions tailored to prospectively identify barriers may improve care and patient outcomes (94). One review evaluated the effectiveness of health care interventions at improving health outcomes and/or reducing diabetes health disparities among racial/ethnic minorities with diabetes. Forty-two studies met inclusion criteria. The review concluded that on average, these health care interventions improved the quality of care for racial/ethnic minorities, found evidence supporting the use of interventions that target patients (primarily through culturally tailored programs),

providers (especially through one-on-one feedback and education) AND health systems (particularly with nurse case managers and nurse clinicians) (95).

Pay for Performance (P4P) and Public Disclosure of health data

Several countries have introduced pay for performance programs for the last years. Under these programmes a portion of payment is dependent on performance assessed against one or more defined measures (65). Italy, Spain, The Netherlands and New Zealand are beginning to reward performance in primary care (96). The UK remains in the vanguard of such schemes, with the Quality and Outcomes Framework (QOF) introducing a P4P system in 2004. General Practices could obtain points by achieving targets for a whole range of quality indicators. HbA1c is one of the indicators. The points serve as a basis to obtain supplementary payments but are also used by the general practices to advertise. This 'Quality and Outcomes' framework probably induced an improvement of the quality of diabetes care. All analyses of the results from the QOF suggest that the program induced a modest positive effect on the quality of care delivered in primary care settings (97). The overall level of achievement of diabetes targets e.g. increased over 4 years, lower-performing practices have shown the greatest improvements, and regional variations in care were reduced (98). There has been a substantial increase in the proportion of all diabetic subjects achieving outcome targets. A more profound analysis of the data confirm the benefits of this Pay for Performance system in the UK, but also indicate that practice performance already improved before the introduction of the QOF, especially for cardiovascular health outcomes. Some indicators also warn for unintended consequences like a decrease in the continuity of care (99). Other more recent studies from the UK and other countries have examined the impact of P4P programs on the quality of diabetes care and suggest significant improvement in comprehensive diabetes care at the physician practice site level (100) and in the intermediate outcomes of diabetes care (101).

In the United States, over 100 private and federal Medicare reward and incentive programmes have been launched. The report "*Rewarding provider performance: aligning incentives in Medicare*." (Institute of Medicine, IOM-2007) has evaluated the literature on P4P and found only fewer than 20 studies, yielding mixed conclusions on overall impact. Some studies have shown a positive effect on the quality of care,

but others have not demonstrated this relationship. In general, the effect of most of these programs has not been examined sufficiently (65). Nevertheless, the report pleads for the introduction of a P4P system in Medicare: *"The systematic and deliberate use of payment incentives that recognize and reward high levels of quality and quality improvement can serve as a powerful stimulus to drive institutional and provider behaviour toward better quality."*

More recent reviews confirm the mixed evidence regarding the impacts of P4P programs (102-104). Some programmes have a large positive effect on the quality indicators but most programs only induce a moderate effect. Until now, negative results were hardly found and unintended consequences seem limited. Though recognizing the probable added value of these programs to shape high performance delivery systems, some authors also warn for unintended consequences and pitfalls pleading for more evidence to understand what works under what circumstances (105).

The IOM- report also stresses the importance of public disclosure of data: "*Beyond merely collecting data on provider performance,* ***Centres for Medicare and Medicaid Services (CMS)*** *should make such data publicly available so that consumers will have the opportunity to fully characterize the performance of providers when making health care decisions. Public disclosure of information, with necessary patient protections, can also stimulate higher levels of quality by showing providers how their performance compares with that of their peers."*

However, evidence in this domain also remains scarce, particularly about individual providers and practices (106). The available evidence suggests that publicly releasing performance data stimulates quality improvement activity at the hospital level. The effect of public reporting on effectiveness, safety, and patient-centeredness remains uncertain. Some studies have shown limited consumer movement following some public reports (107). There is also some evidence that making hospital quality reports public provides an independent stimulus to quality improvement efforts, above and beyond the effect seen with private reports (108-110). The beneficial impact of public reporting was evaluated as rather small but real, positive effects mediated through both likely mechanisms by which public reporting may improve quality—consumer recognition of performance differences and provider

efforts to improve—have been found. On the other hand, some evidence showed that providers may attempt to avoid sick patients or manipulate the documentation of patients' clinical status (111).

Furthermore, public reporting probably could be a part of a larger pay for performance program as a study evaluating changes in adherence to quality measures at 613 hospitals that voluntarily reported information about the quality of care found modestly greater improvements in quality of care in hospitals that engaged in both public reporting and pay for performance than did hospitals engaged only in public reporting (112).

Quality Improvement Trials for people with diabetes

In order to benchmark the over-time improvement of the primary outcomes (HbA1c, LDL-Cholesterol and Systolic Blood Pressure) in both intervention groups of the Leuven Diabetes Project, we conducted a narrative review of original trials implementing quality improvement interventions in primary diabetes care. We made a search in Medline and Embase.

We found 68 original studies with 45 RCT's (addendum at the end of this chapter). 59 reported on continuous outcomes, 9 only reported on dichotomous outcomes (addendum). We found thirteen clinician-centred interventions, three organizational interventions, 28 patient-centred interventions and 24 multi-level interventions. We did not find any study regarding the effect of peer support on patient outcomes. To our knowledge, one study on this issue is ongoing (113). One of the included studies has not been published yet in a journal, but is extracted from a PhD-thesis: "Disease management for patients with Type 2 Diabetes: towards patient empowerment" (Laura Welschen, 2008, Vrije Universiteit Amsterdam).

54 studies included data on both the mean baseline value and the mean change over time of HbA1C. 9 studies included data on the baseline proportion of patients reaching a target (8 with HbA1C-target of 7% and 1 with a target of 7.5%). Only 24 studies included data on Cholesterol values (mostly Total Cholesterol) and 8 studies included data on the proportion of patients reaching predefined Total Cholesterol targets (5) or LDL-targets (3). 30 studies included data on Systolic Blood Pressure values and 6 on the proportion of patients reaching a predefined SBP target.

25 studies (16 RCTs, 4 NRCTs) showed significant differences between the intervention and the control group for at least one of three endpoints. The mean baseline value of HbA1c, LDL-C, Total Cholesterol and Systolic Blood Pressure in the included studies was respectively 8.3%±1.3, 118± 17 mg/dl, 207±20 mg/dl and 142±8 mm hg. The mean change over time was respectively -0.5%±0.6%, -11±8 mg/dl, -15±10 mg/dl and -4±4 mm Hg. Regarding HbA1c, most (N= 41) studies started with baseline values <8.5%. Most of these studies showed only show small HbA1c improvements (< 0.5%). Only 1 study showed an improvement of -1.5%, but this improvement was not significant better than the improvement in its control group. Almost all studies with a more than moderate clinical effect (improvement > 0.5%) started with baseline values > 8.5%. On the other hand, 3 of the included studies started with very high baseline HbA1C-values (HbA1c > 11%) and showed only modest improvement. Only one of them showed a significant improvement compared to the control group. The mean HbA1c improvement in studies with baseline values ≤ 7.5% was -0.1±0.3% (N=15) versus a mean improvement of -0.7±0.7% in studies with baseline values > 7.5%. We found a highly significant correlation between the mean baseline Hba1c values and the change over time (correlation coefficient -0.664, p<001; N=55). We also found a highly significant correlation between the change over time of SBP and baseline values (correlation coefficient = -0, 59, p=0.001, N=30).

Summary of the evidence

This narrative review of trials and systematic reviews on quality improvement confirmed the viewpoint of Shojania et al. that many quality improvement interventions in diabetes care only showed small improvements in patient outcomes. Clinically important improvements are mostly found in studies with high baseline values. The most robust improvements have been noticed by team changes, self-management support and multifaceted improvement programs implementing the Chronic Care model. Pay for Performance, eventually with additional public disclosure of performance data is a promising initiative to improve the quality of chronic care.

BOX 2: EPOC Taxonomy Used to Classify Quality Improvement Strategies (reprinted from Shojania et al.) (25)

Audit and Feedback. Summary of clinical performance of health care delivered by an individual clinician or clinic over a specified period, which is then transmitted back to the clinician (eg,the percentage of a clinician's patients who have achieved a target glycosylated hemoglobin [HbA1c] level, or who have undergone a dilated-eye examination with a specified frequency).

Case Management. Any system for coordinating diagnosis, treatment, or ongoing patient management (eg, arrangement for referrals, follow-up of test results) by a person or multidisciplinary team in collaboration with or supplementary to the primary care clinician.

Team Changes. Changes to the structure or organization of the primary health care team, defined as present if any of the following applied:

• Adding a team member or "shared care," eg, routine visits with personnel other than the primary physician (including physician or nurse specialists in diabetic care, pharmacists, nutritionists, podiatrists).

• Use of multidisciplinary teams, ie, active participation of professionals from more than 1 discipline (eg, medicine, nursing, pharmacy, nutrition) in the primary, ongoing management of patients.

• Expansion or revision of professional roles (eg, nurse or pharmacist plays more active role in patient monitoring or adjusting medication regimens).

Electronic Patient Registry. General electronic medical record system or electronic tracking system for patients with diabetes.

Clinician Education. Interventions designed to promote increased understanding of principles guiding clinical care or awareness of specific recommendations for a target condition or patient population. Subcategories of clinician education included conferences or workshops, distribution of educational materials, and educational outreach visits.

Clinician Reminders. Paper-based or electronic system intended to prompt a health professional to recall patient-specific information (eg, most recent HbA1c value) or to perform a specific task (eg, perform a foot examination). If accompanied by a recommendation, the strategy would be subclassified as decision support.

Facilitated Relay of Clinical Information to Clinicians. Clinical information collected from patients and transmitted to clinicians by means other than the existing medical record. Conventional means of correspondence between clinicians were excluded. For example, if the results of routine visits with a pharmacist were sent in a letter to the primary care physician, the use of routine visits with a pharmacist would count as a "team" change, but the intervention would not also be counted as "facilitated relay." If, however, the pharmacist issues structured diaries for patients to record self-monitored glucose values, which are then brought in person to office visits to review with the primary physician, then the intervention would count as "facilitated relay." Other examples include electronic or Webbased tools through which patients provide self-care data and which clinicians review,23-25 as well as point-of-care testing supplying clinicians with immediate HbA1c values.26

Patient Education. Interventions designed to promote increased understanding of a target condition or to teach specific prevention or treatment strategies, or specific in-person patient education (eg, individual or group sessions with diabetes nurse educator; distribution of printed or electronic educational materials). Interventions with patient education were included only if they also included at least 1 other strategy related to clinician or organizational change.

Promotion of Self-Management. Provision of equipment (eg, home glucometers) or access to resources (eg, system for electronically transmitting home glucose measurements and receiving insulin dose changes based on those data) to promote self-management. Interventions promoting patient self-management were included only if they also included at least 1 other strategy related to clinician or organizational change.

Patient Reminder Systems. Any effort (eg, postcards or telephone calls) to remind patients about upcoming appointments or important aspects of self-care. Interventions with patient reminders were included only if they also included at least 1 other strategy related to clinician or organizational change.

Continuous Quality Improvement. Interventions explicitly identified as using the techniques of continuous quality improvement, total quality management, or plan-do-study-act, or any iterative process for assessing quality problems, developing solutions to those problems, testing their impacts, and then reassessing the need for further action.

Box3. Other relevant terminology

Quality improvement collaborative: defined as fulfilling the following five criteria: (1) a specific topic is addressed, there is major variation between current and best practice; (2) clinical and quality improvement experts provide ideas and support for improvement; (3) there is cooperation between interdisciplinary teams on multiple sites; (4) a model for improvement sets targets and measures change; (5) and the collaborative process involves a series of structured activities within a set timeframe.(90)

Shared care: the joint participation of primary care physicians and specialty care physicians in the planned delivery of care, informed by an enhanced information exchange over and above routine discharge and referral notices. It has the potential to improve quality and coordination of care delivery across the primary-specialty care interface.

Pay for Performance: payment is dependent on performance assessed against one or more defined measures.

Section 6. Background of data collection: the Leuven Diabetes Project

The data for this PhD project were collected from the Leuven Diabetes Project (LDP), a large federal state funded Quality Improvement Program in Belgium and a pilot project to examine the usefulness and feasibility of a nation-wide implementation of quality improvement initiatives in the care of chronic diseases.

The project was constructed on the two before mentioned theoretical frameworks. The *quality improvement interventions* were based on the Chronic Care Model. These interventions however were part of a *larger implementation plan*. This plan was based on the methodological framework described in the implementation model.

The trial was conducted from January 2005 until December 2006 and included 120 primary care physicians and 2495 predominantly Caucasian patients with Type 2 Diabetes Mellitus. These physicians work in a semi-rural setting with 357.000 inhabitants surrounding the University Hospitals of Leuven. The objective of the LDP was to improve patients' outcomes through support measures for general practitioners and patients. The LDP was a cluster-randomized trial with before/after measurements, two intervention arms and an implementation period of 18 months. The first intervention arm received a Usual Quality Improvement Program (UQIP-program), which was a set of interventions addressing the principal barriers to quality improvement: the diffusion of an evidence-based treatment protocol, annual benchmarking, postgraduate education, case-coaching for GPs and the possibility to refer for patient education. The second arm received an Advanced Quality Improvement Program (AQIP-program) that included supplementary initiatives focusing on intensified patient follow-up, protocol based shared care and special attention to patient behavioural changes.

Section 7. Aim and Research Questions

General objective of the PhD project.

The general research objective of this PhD Project **is** to assess the quality of care for patients with Type 2 Diabetes, to evaluate the effectiveness of quality improvement measures in the Belgian health care setting, and to place this in the context of the challenges for chronic care re-organization.

Diabetes in this thesis will be considered as a high cardiovascular risk equivalent. Therefore, quality of care will primarily be measured by "*patients' intermediary outcomes*", which are defined as all parameters at patient level affecting the co-morbidity risk of diabetes: lifestyle attitudes (smoking status, physical exercise, diet and food patterns), biological and biochemical parameters (Body Mass Index, lipid values, blood pressure and HbA1c for glycemic control) and drugs directly affecting cardiovascular disease (statins, ACE-inhibitors, anti-platelet therapy). The primary outcomes throughout the project are HbA1c, Systolic Blood Pressure and LDL-C.

Secondarily, process parameters (statin therapy, insulin therapy, indicators for the screening of complications) will be taken into account to measure the evolution of quality of diabetes care.

Research question per chapter

I	*Research Question*	What is the quality of diabetes are as measured by patients' intermediate outcomes in a Belgian health care setting?
	Method	Cross-sectional study analyzing quantitative data that were collected at baseline of the "Leuven Diabetes Project evaluating the 'usual' care in a Belgian region without any experimental intervention or guideline implementation.
II	*Research Questions*	(1) Can improved quality of care be achieved with a basic support program for GPs and patients (UQIP), (2) Can an intensified support of GPs and patients in the AQIP arm paying special attention to shared care, patient compliance and adherence to lifestyle changes further improve outcomes in T2DM patients achieved by the UQIP?
	Method	Cluster randomized trial with two intervention arms, a basic intervention arm (UQIP) and an intensive intervention arm (AQIP)

III	*Research Questions*	(1) What is the five year (2002 – 2007) evolution of the quality of diabetes care in a region that was the setting of an experimental Quality Improvement Program (LDP) for a part of the diabetes population during the last two years of this registration period? (2) Is the evolution of the quality of care for patients clustered around GPs who participated in the LDP significant different from the evolution of parameters of patients clustered around GPs who did not participate?
	Method	Analysis of insurance claims data of people with Type 2 Diabetes taking glucose lowering medication and living in the region of Leuven. 'Diabetes Care' will be evaluated both by analyzing available intermediate outcomes (HbA1c, LDL-C, HDL-C and Triglycerides) and process parameters.
IV	*Research Questions*	(1) What changes did GPs participating to an 18 month Quality Improvement Program actually perceive? (2) What are the barriers and facilitators to high-quality diabetes care as they were experienced by participating GPs.
	Method	Qualitative Study that was nested in the controlled trial of the LDP by interviewing GPs who participated in the 18-month Quality Improvement Program.
V	*Research Question*	What is the added value of a composite metric based on HbA1c, LDL-C and SBP in the daily monitoring of General Practices?
	Method	Development of a composite indicator and validation of this indicator by testing it on the cohort population of the 'Leuven Diabetes Project'.

Addendum: Quality improvement interventions in primary care

Study	Country & setting	Study design	Sig, Δ	Follow-up (mo)	type	Level	Intervention	N (IG)	A1c-BL	Δ_T A1c Δ_C A1c	LDL-BL	Δ_TLDL Δ_CLDL	TC-BL	Δ_TTC Δ_CTC	SBP-BL	Δ_TSBP Δ_CSBP
Hetlevik(114)	Norway, 29 centres and 53 (24 + 29) doctors	RCT	No		S	C	Computer based clinical decision support	499	8,2	-0,3 -0,1					153	-1 -1,2
Kinmonth 1998(115)	England, 41 GP practices (21 IG)	RCT	No	12	S	C	Training in patient centered care	250							144	0 -2
Meigs, 2003(116)	Massachusetts, USA	RCT	no	12	S	C	Web-based decision support tool		8,4	-0,2 -0,3	127	-15 -4			138	+1 +3
Van Bruggen(117), 2008	Netherlands,30 GP practices	RCT	No	12	MF	C	Structured care, clinician education, performance feedback: MF	822	7,0	-0,1 0			205	-8 -4	146	0 -1
Phillips(118)	Atlanta, USA, 345 internal residents (generalists in training)	RCT	Yes	36	MF	C	Computerized reminders, feedback, clinician education	1063	8,0	-0,54 -0,38	122	-19 -3			138	-3 -1
Cleveringa(119), 2007	Netherlands, 113 PC practices	Before / after	NA	24	MF	ML	Practice reorganization (task delegation to nurse), computerized decision support	7893	7,0	-0,2			201	-15	149	-6
Mackey(120)	Texas, USA, university PC practice	Before / after	NA	12	MF	ML	CCM: multifaceted (delivery system redesign, provider education, practice nurse), self-evaluation	44	7,7	-0,3	123	-25			126	+5
Reed 2001(121)	United Arab Emirates, primary care	Controlled before/after	no		MF	ML	Diabetes clinics created with guidelines, patient education, appointments, clinician education and access to specialist care	109							129	-2 +1
Vargas(122)	Los Angeles, USA	Controlled before/after	No	12	M	ML	CCM: collaborative learning sessions to implement CCM	613	7,9	-0,5 -0,24	111				138	-2,4 -0,4
Balamurugan (123)	Arkansas, USA	Controlled before/after, participants vs, nonparticip	?	12	MF	ML	Diabetes Self-management Education in continuous quality improvement process: 12 hours course	201	8,0	-0,45					141	-4

		ants)														
Grant(124)	Massachusets, USA, 4 primary care clinics	Non RCT	No	20	MF	ML	Software diabetes registries and population management	898	7,9	-0,3 -0,1	106	-11 -1			133	-3 -1
Lim 2002(125)	Singapore, Primary Care	Non RCT	NA	6	MF	ML	Disease management: case management with PCP, case manager, podiatrist, dietitian, patient education, provider reminders	63	9,8	-2,0					142	-8
Hirsch(126)	Washinton, USA, Academic family practice	Non RCT	Yes	14	MF	ML	Reminders, diabetes management protocol review, clinician education, feedback, case management, coaching	65	7,6	-0,1 -0,7			203		135	-1
Olivarius(127)	Danmark, 311 practices, 474 GPs (243 +231)	Non RCT	Yes	72	MF	ML	Structured personal care: individualized goal setting, prompting of doctors, guidelines, feedback and clinician education	649	10,2	-1,7 -0,5			240	-8 -4	150	-5 -7
Groeneveld(128)	The Netherlands, 15 (8 +7) GPractices	RCT			MF	ML	Diabetes education (nurse, dietician), call/recall system every 3 months or more	91	?	?			240	-4 0	137	-2 +4
O'Connor(129)	Minneapolis, USA, 12 PC practices	RCT	No	18	MF	ML	Seven step QI process: clinician education, teams (nurse, staff, physician), meetings	428	8,1	-0,1 +0,1	133	-16 +4			136	-1 0
O'Hare(130), 2008	UK, south Asian pop, 21 PC, practices	RCT	No	24	MF	ML	Enhanced care: practice nurse, link workers, community nurse, language	868	8,2	+0,04 -0,15			182	-17 +1	139	-5 0
Smith 2004(131)	Dublin, Ireland, 38 GPractices, 50 GPs	RCT	no	18 months	MF	ML	Structured shared care: clinician education, diabetes specialized nurse, guidelines, review by specialist, record cards, referral system	96	6,9	+0,1 0			205	-4 -4	162	-4 0
Wagner 2001(66)	Primary care practices, HMO, USA	RCT	No	24	MF	ML	Chronic Care clinics for groups of 8 patients	278	7,5	+0,4 -0,1			215	-13 0		
O'Hare(132)	UK, south asian ethnicity 6 (3 +3) practices	RCT	Yes	12	MF	ML	Enhanced diabetes care: asian link workers, practice nurse, diabetes specialist	165	7,8	-0,2 0			213	-19 -14	146	-7 -5

							nurse, protocols with treatment targets									
Peterson(133), 2008	Minnesota,USA, 24 PC practices, 238 providers	RCT	Yes	24	MF	ML	CCM with diabetes registry, clinician reminders, proactive planning	3970	7,25	+ 0,01 -0,03	104	- 4 0			133	- 1,3 +0,2
Piatt(134)	Pittsburg, USA, 11 PC practices	RCT	yes	12	MF	ML	CCM: community partnerships, self-management support, process redesign, clinician education, diabetes educator, feedback,	30	7,6	-0,6 -0,6	154	-11 -9			143	-1 0
Rothman 2005(135)	Tennesse, USA, primarcy care	RCT	yes	12	MF	ML	Pharmacy-led sisease management program, educational sesions, EB algorithms, pro-active management	99	11	-2,5 -0,8			213	-27 -15	140	-4 -5
Varrroud-Vial(136)	France, 57 GPs	RCT	yes	12	MF	ML	Diabetes management: clinician education, decision support tools (booklet)	192	7,5	-0,3 -0,8	132	-7 +10	215	-9 +1	141	-4 -2
Majumdar(137)	Canada, rural patients	Controlled trial (region based)	no	6	S	O	6 monthly visit of specialist team	200	7,2	?			188		130	?
Branger, 1998(138)	The Netherlands	RCT	No		S	O	Electronic communication systems between primary and secondary care		7,0	-,02						
Litaker(139)	USA	RCT	yes	12	S	O	Practice nurse	79	8,4	-0,63 -0,48			212	-11 -1		
Clifford 2002(140)					S	P	Pharmacist monitored patients		8,4	-0,2 +0,2						
Coast-Senior(141)	USA, VA	before/ after			S	P	Educational intervention to improve adherence to treatment recommendations in Type 2DM patients: Face to Face, pharmacist led	23	11,1	-2,2						
Miller 2003(142)	PC clinic, Atlanta USA	Non RCT	no	24	S	P	Rapid A1 measurement	317	8,5	-0,2 -0,3						
Van Welschen (in submission), thesis	The Netherlands, General Practices	Non RCT	no	12	S	P	cognitive behaviour therapy (CBT) in addition to managed care, and a control group that will receive managed care only.	76	6,8	0 -0.1	89	-8	170	-12 -4	145	-1 +2

							The CBT consists of three to six individual sessions of 30 minutes to increase the patient's motivation, by using principles of MI (motivational interviewing), and ability to change their lifestyle, by using PST (problem solving treatment).									
Gilliland 2002(143)	USA, native people, community	Non RCT	yes	12	S	P	Culturally appropriated education: FF: family and friends O&O: on in one	71 32 39	8,3 9,2	+0,5 +0,2			199 218	-22 -20		
Cooper 2003(144)	Liverpool, UK	RCT	No	12	S	P	"Diabetes Look After Yourself" course, self-management given by specialist diabetes nurses	53	7,9	0 -0,2						
Davies 2008(145)	UK, primary care (DESMOND)	RCT	no	12	S	P	A structured group education programme for six hours delivered in the community by two trained healthcare professional educators compared with usual care.	387	7,9	-1.5 -0.3	128	-29 +6	209	-37 0	140	-6 0
Goudswaard 2004(146)	The Netherlands	RCT	No	18	S	P	Education and self-management	28	8,2	-0,4 +0,2						
Krier199(147)	USA, setting unknown	RCT	no		S	P	Quarterly visits by the diabetes educator	21	9,6	-0,4						
Piette 2001(148)	USA, VA patients	RCT	No	12	S	P	Automated Telephone Disease Management: patient calls with information and then telephone follow-up by nurse	272	8,2	-0,1 -0,2						
Piette, 2000(149)	USA, county health system	RCT	No	12	S	P	Automated Telephone Disease Management: patient calls with information and then telephone follow-up by nurse	280	8,8	-0,6 -0,3						
Pouwer(150)	Amsterdam, outpatients,unive	RCT	no	12	S	P	Psychological monitoring and counseling by psy if	191	7,8	-0,1 0						

	rsity clinic						judged necessary									
Ridgeway 1999(151)	USA, community (ROMEO)	RCT	no	12	S	P	Nurse and dietitian led education on diet an exercise	28	12,3	-0,8 -0,1	133	-3 -9	259	-40 -50		
Samuel-Hodge 2009(152)	USA, Afro-Americans	RCT	no	8	S	P	Church-based educational intervention	117	7,8	-0,4 0						
Aubert 1998(153)	USA	RCT	yes	12	S	P	nurse case management diabetes program that included close follow-up, continuous reinforcement of meal planning and exercise, and systematic treatment adjustments	71	9,0	-1,7	126	-6	211	-12		+1,9
Brown 2002(154)	USA	RCT	yes	12	S	P	Culturally competent Diabetes self-management Group education	128	11,8	-0,9 -0,7			211	-21 -4		
Brown 2005(155)	USA	RCT	yes		S	P	Culturally competent Diabetes self-management Group education	114	11,5	-1 -0,3						
Deakin 2006(156)	UK, primary care	RCT	yes	14	S	P	Group based education and self-management on nutrition, weight, exercise, complications, goal setting and self-monitoring	157	7,7	-0,6 -0,7	104	0 0	197	-12 -8	148	-7 -3
Denver 2003(157)	PC	RCT	yes	6	S	P	Nurse-led clinic Patient education	120	8,2	0 0			189	-4 0	161	-20 -13
Hee-Sung 2007(158)	Korea	RCT	yes		MF	P	web-based education, use of cellular phone by nurse	25	8,1	-1,1 -0,8						
McMahon(159)	Massachusetts, USA, VA-practice, poorly controlled patients	RCT	Yes	12	MF	P	Web-based care management: patients receive notebook, glucometers and BP monitor	52	10	-1,6 -0,4	141	-6 -1			141	?
Oh 2003(160)	Korea	RCT	yes	3	S	P	Patient Telephone calls to monitor BG, diet, exercise and medication adjustments	20	8,9	-1,2 +0,8						
Sadur 1999(161)	USA, Health maintenance (Kaiser Permanente)	RCT	yes	6	MF	P	Multidisciplinary outpatient care management by nurse, psychologist, dietitian and pharmacist in	82	9,5	-1,3 -1,1						

							cluster visits (10-18 patients)									
Sarkadi 2004(162)	Sweden	RCT	yes	24	MF	P	experience-based group educational programme, pharmacist-led, also nurse (self-management on lifestyle and self-monitoring)	39	6,5	-0,4 -0,5						
Shea 2007(163)	New York	RCT	yes	12	MF	P	1. Videoconferencing 2. Remote glucose monitoring 3. Electronic access to own clinical data 4. Web-based education	670	7,4	-0,4 -0,2	106	-10 -8	183	-12 -10	142	-5 -4
Trento 2004(164)	Italy	RCT	***Yes***	60	S	P		112	7,4	-0,1 -1,8			225	-13 +4		
Trento 2008(165)	Italy	RCT	yes	24	S	P	Group care by nurse, pedagogist and dietitian	25	8,0	-0,4			197	-4	145	-9
Izquierdo 2003(166)	USA, New York, VA	RT, nurse education vs. telemedicine education	no		S	P	Nurse education (control), vs. telemedicine education (intervention)	24	8.7	-0,9 -0,1	110	-14 -9				
Smith 2008(167)	USA Mayo Clinic	RT	no	29	S	C	Specialty telemedicine advice to GP	358	7.3	-0.6	104	-12			130	-1
Holbrook 2009(168)	Toronto, Canada	RT	yes	6	S	C	Electronic decision support and reminders	253	7.0	-0.2	93	+1			135	-4
O'Connor 2009(169)	Minneapolis, USA	RT	no	12	S	C	Simulated physician learning with expert input	604	7.3	+0.2	105	-4				
O'Connor 2009(170)	Minneapolis, USA	RT	no	12	S	ML	Customized feedback to patients and providers	656	7.5	-0.1	129	-24				

Δ = change over time ; Δ_T = change over time in the intervention group
Δ_C = difference in change over time between the intervention and the control group (if applicable)
BL = baseline ; Mo = months ; Sig.Δ = significant difference with control group for primary outcomes
Type of intervention: MF = Multifaceted ; S =single intervention
IG = Intervention Group
P4Q = Pay for Quality/ P4P = Pay for performance
Total and LDLC units have been recalculated in mg/dl if mentioned in mmol/l
Level: P = Patient ; C= clinician (GP,PCP) ; O= Organizational ; ML = Multilevel (at least 2 of the three levels)

Study	Country	Study design	Sig, Δ with control group for primary outcomes?	Period months	Kind Int	Level	intervention	N (IG)	HbA1 Target (%)	% AT BL HbA1c	Δ	Chol Target (mg/dl)	%AT BL Chol	Δ	(S)BP Target (mm Hg)	%AT BL (S)BP	Δ
Ornstein2007 (171)	USA, 66 practices, 372 providers	Before / after	?	18	MF	C	Audit, feedback, practice site visits, network meetings (PPR-net)	24250	7	:47	+4	LDL 100	39	+13	130/80	53	+6
Coleman 2007(172)	Chicago	Before/after	NA	12	S	C	P4P	1166	7	32	-6						
Vaghela(98), 2009	UK, 98% of all English PC practices	Longitudinal observational		48	P4P	C	P4Q	1,000,000	7,5	59	+8	TC: 193	73	+11	145/85	71	+9
Ornstein2004	USA,multi-center, 20 practices, 44 physicians	RCT	No	24	MF	C	Practice guidelines, feedback, practice visits, network meetings	45571	7	49	+5	LDL: 100	45	+12	140/90	64	+8
Ilag(173)	Michigan, USA, 9 practices	RCT	No	24	S	C	Annual assessment with feedback	103	7	34	-6	LDL 100	52	-4	135	66	-6
Renders 2001	The Netherlands, General Practice	Non randomized controlled trial	No	42	MF	ML	Clinician education, audit and feedback, relay of data	312	7	41	+4	TC 200	21	+7	140	31	+12
Valk(174)	Netherlands, 22 GPs	Observational	NA	60	MF	ML	Medical record system, clinical practice guidelines, physician	379	7	54	-12	TC 200	15	+8			

							education, audit, feedback, recall system										
Valk(174)	USA, 50 GPs	Observational	NA	60	MF	ML	Medical record system, clinical practice guidelines, physician education, audit, feedback, educational outreach visits, multidisciplinary teams, patient SME	2119	7	32	-15	TC 200	23	+17			
Ubink-Veltmaat (175)	The Netherlands, 32 (+21 +8) practices	Observational study, controlled	NA	36	MF	ML	Structured shared care intervention: diabetes register, structured recall, generalist-specialist communication, feedback, reminders and patient education	1244	7	43	-1	TC: 193	28	+12	150/85	:40	+12

IG = intervention group; N above = patients ; below = practices: %AT = % of patients at target ; Δ = change over time in % of patients at target

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Chapter 1: Type 2 Diabetes in primary care in Belgium: need for structured shared care.

Goderis G, Borgermans L, Heyrman J, Broeke CV, Grol R, Boland B et al. Type 2 Diabetes in primary care in Belgium: need for structured shared care. Exp Clin Endocrinol Diabetes 2009; 117(8):367-372.

Abstract

Objective: To picture the profile of Type 2 diabetic patients in Belgium and to study the quality of care in primary care setting, with regard to multi-factorial approach of the disease.

Methods: Observational study of all known T2DM-patients registered by 120 volunteer general practitioners. Quality of care was evaluated by the achievement of three major treatment targets: HbA1c <7%; Systolic Blood Pressure ≤130 mmHg; LDL-Cholesterol <100mg/dl (ADA 2003). Multivariate analysis was performed.

Results: 2495 T2DM-patients were included with a mean age of 68±12 years and 51% being women. One fifth of patients had microvascular complications and 27% had macrovascular complications. Sixty eight percent received oral anti-diabetic drugs and 19% were on insulin. Satisfactory glycemic control (HbA1c<7%) was achieved in 54% of the patients, with however glucose control deteriorating with disease progression despite more intensive hypoglycemic treatment. Systolic blood pressure targets were reached in 50%. Statin use was present in 39% and LDL levels <100mg/dl were reached in 42%. 59% of insulin treated patients were followed up in shared care with specialized diabetes centres. These patients obtained lower values for HbA1c (7.5±1.2% vs. 7.8±1.5%, p=0.038) and LDL-C (90±34 vs. 111±37, p<0.001) compared to insulin-treated patients only followed up in primary care.

Conclusion: Overall metabolic control in Type 2 Diabetes patients in primary care in Belgium was acceptable for glucose control, but major room for improvement exists especially for statin use and blood pressure control. Clinical inertia is present and the presence of more structured care in specialized diabetes centres, focusing on therapeutic guidelines, may explain the better overall metabolic control in patients followed up in shared care with these centres.

Keywords: Diabetes, Type 2; Primary Care; Cardiovascular Disease; Quality of Care; Cross-Sectional Studies

Introduction

Type 2 Diabetes Mellitus is a major threat to global public health with micro- and macrovascular complications being highly prevalent. Approximately 2.9 million deaths per year worldwide are attributable to diabetes (1), part of while could be prevented by lifestyle measures and pharmacological therapy (2). A second problem is the steep increase in numbers of patients with diabetes. By 2025, more than 10% of the adult population will be affected by the disease, reaching over 300 million individuals worldwide (3). This will lead to major challenges for health care management. The most recent international guidelines recommend an intensive and global follow-up of all Type 2 Diabetes patients once the disease has been diagnosed (4;5). In order to cope with a disease of these dimensions, health care systems will have to introduce new approaches, such as shared care treatment protocols and adapted organizational structures and especially, the involvement of general practitioners, preferentially assisted by specialized nurses or diabetes educators. Nevertheless, despite the necessity of an explicit task division and job sharing between the General Practitioner and the endocrinologist (6), no evidence based consensus so far exists (7).

Furthermore, in many countries, like Belgium, France or Germany, the traditional primary health care system is poorly adapted to coping with this upcoming chronic disease epidemic (8;9). GPs mostly work in solo-practices (10), without additional staff, rather demand driven, without a chronic care tradition based on diabetes patient registries or organized diabetes consultations. Shared care at primary care level is loosely organized since GPs cannot rely on structured assistance of dieticians or diabetes nurse educators in their practice. Moreover, in some countries such as Belgium, patients have to make considerable financial contributions for out-practice dietetic services and materials needed for self monitoring. In Belgium, the GP has no gatekeeper function and thus all patients theoretically can make an appeal to an endocrinologist for their diabetes treatment. In addition, the Belgian law allows some patients, those treated by multiple daily insulin injections, to contractually adhere to such a centre enabling the possibility of an intensive management by a multidisciplinary diabetes team including diabetes nurse-educators and dieticians, led by the endocrinologists. Patients adhering to this system do receive reimbursement of diabetes education and self monitoring

materials. Structured recall systems invite them to the centre and multidisciplinary embedding in the hospital is present, with access to specialized advice, e.g. cardiology, podiatry and nephrology. A quality-monitoring system (IKED) which has been in place for 10 years has contributed to the optimal organization of care for this subset of patients (11).

The present study evaluated the 'usual' care in a Belgian region without any intervention or guideline implementation and allows evaluating the main patient outcomes in a health care system characterized by a loosely organized primary care with however a task division between primary care and diabetes centres. Most patients are primarily treated by the GP, whereas a minority of patients, those on multiple daily insulin injections is treated in shared care with diabetes centres. In the present study, attention was not only focused on glycated hemoglobin (HbA1c), often used as the gold standard of metabolic control. Several other outcome and process measures that give an integrated view of diabetes care were assessed, especially blood pressure and lipid profile levels and actions to control them, which are important determinants of cardiovascular mortality and morbidity (12).

Patients and Methods

Study description and data collection

Data were collected in a cross-sectional design at baseline of a clustered randomized intervention, the Leuven Diabetes Project (LDP). The study was performed in a region of 357,000 inhabitants that surrounds the medical university hospital of Leuven. This particular region was chosen because of its semi-rural, semi-urbanized character. All primary care physicians of the region were invited to participate in the LDP. A fixed fee of 60 Euro was issued per registered patient. In order to prevent selection bias, physicians agreed to register all their known type-2 DM patients including those who were adhering to specialized diabetes centres. Diabetes was diagnosed according to ADA guidelines (13). Patients with diabetes were identified using electronic searching in computerized records and laboratory lists of patients with increased glycemia or registered HbA1c. Patient data were collected on a paper sheet from January to July 2005 and the completeness of data capture was double-checked by a data monitor. In order to obtain the requested data, physicians

performed an in-depth anamnesis and a complete examination including a blood analysis at patient's first visit during the registration period. Blood Pressure measures were taken by the GPs either at the office or at patients' home. GPs received detailed written instructions with the WHO/ISH criteria for correct blood pressure measurement and received a short training course at the beginning of the project. Patient data sheets included several sociological, biomedical and medication parameters. Laboratory data were registered by GPs referring to their usual laboratory, thus involving seven laboratories. However, 97% of the HbA1c analyses were performed in three laboratories, using the same HPLC-technique (Menarini HA-81.60™, Menarini Diagnostics, Florence, Italy) with reference values between 4 and 6%. Three laboratories used other DCCT standardized analyzers (1 HLC-723 GHbG7, Tosoh Bioscience Corporation, Tokyo, Japan; 1 VARIANT TM II TURBO Hemoglobin Testing System, Bio-RadLaboratories, Hercules, USA; 1 ADAMS™A1c, HA-8160, Arkray inc., Kyoto, Japan) again with reference values between 4 and 6%. Only one laboratory, reflecting measurements for 12 patients presented with reference values between 4 and 6.6% (Menarini HA-81.40, Menarini Diagnostics).

For the involved patients, the presence of shared care with contractual adherence to a diabetes centre was registered. The presence of CVD (14) was pre-defined as a reported history of heart attack, cerebrovascular disease, and history of angina, PAD or coronary, cerebral or peripheral vascular intervention in the personal history. The LDP-study has been approved by the ethical committee of the Catholic University of Leuven (project number ML 2719)

Outcomes and statistical analysis

The study focused primarily on three patient outcomes: HbA1c for glycemic control, Systolic Blood Pressure (SBP) for blood pressure profile and Low Density Lipoprotein-Cholesterol (LDL-C) for lipid profile. Mean values as well as the proportion of patients reaching the ADA-targets were evaluated [HbA1c <7%; SBD ≤ 130 mm Hg; LDL-C <100mg/dl]. Secondly, treatment with essential cardiovascular drugs like statin and anti-platelet therapy was evaluated. Finally, the relationship between diabetes duration, glucose lowering therapy and outcomes was examined. Exploratory means and standard deviations were reported for continuous variables. Proportions were reported for categorical variables. The clustered nature of the study (all patients around their physicians) was accounted for in multilevel analyses, with

random physician effect. These models allow for variability between physicians as well as variability between patients (within physicians). For continuous outcome variables, linear mixed models were fitted using restricted maximum likelihood estimation. Dichotomous and ordinal outcomes were analyzed using logistic and proportional odds mixed models, respectively. Model estimation was then based on maximum likelihood, with Gaussian quadrature with 200 quadrature points for the approximation of the likelihood. Analyses were performed using SAS statistical software package, with the procedure MIXED for the linear models and NLMIXED for the others. All tests are based on the 5% level of significance.

Concerning the three main parameters (HbA1c, LDL-C an SBP), multiple regression models were used to study the joint association between the outcomes and all predictors, with additional correction for patients' age, gender, diabetes duration, BMI, history of CVD, hypoglycemic treatment, patient's motivation, presence or absence of depression, shared care with a diabetes centre and for GP's workload, gender, use of electronic medical file and practice type (solo/duo/group).

The models compare patients on insulin treated by the GP with patients taking no antidiabetic drugs and patients with OADs, also treated by the GP. Insulin treated patients adhering to a diabetes centre were separately compared with patients on insulin treated by the GP.

Since not all variables were available for all patients, case-wise deletion was used. However, since all analyses are likelihood based, valid inferences can still be obtained under the assumption of random missingness, i.e., the fact that a variable is missing for a patient is unrelated to the outcome that would have been measured for that patient.

Results

Within a three-month inclusion period 120 physicians (32%) agreed to participate. Mean physician's age was 44±10 years with 45% female doctors. 38% of the physicians worked solo, 32% worked in a duo and 30% in a group practice (3 or more physicians). Mean number of patient contacts per week was 95±29 per physician corresponding to a practice population of 760 patients. Nearly all physicians (91%) used a computerized record. Present study included 2495 patients with a mean number of 21 patients per physician and a range from 2 to 73. The

estimated practice prevalence of Type 2 Diabetes patients is 2.8%. As table 1 indicates, we deal with an older population with only 9% of the patients younger than 50 years, 40% older than 72 years and 14% older than 80 years. Overweight and obesity were highly prevalent with 82% having a BMI > 25 and 43% >30 kg/m². Mean fasting glycemia and HbA1c were 139±47 mg/dl and 7.15±1.3%, respectively. Mean blood pressure was 136/79 ± 16/10 mm Hg with 73% of patients under antihypertensive drug treatment. Mean total cholesterol, LDL- and HDL-cholesterol was 192±40 and 108±34 and 54±16 mg/dl, respectively. Statins were prescribed in only 39% of the total population.

Diabetes complications were highly prevalent: 27% of the patients had macro-vascular disease : myocardial infarction 11%, angina pectoris 14%, stroke 7%, PAD 7%, with 15% of the population having received a cardiovascular intervention. One fifth of the patients had micro-vascular complications: nephropathy 12%, retinopathy 10%, neuropathy 10% and diabetes foot problems 4%.

Most patients were treated with OADs, being metformin, sulfonylurea or thiazolidinediones. Thirteen percent were on lifestyle interventions only, taking no antidiabetic drugs. Nineteen percent (N = 482) received insulin treatment most of which (12%, N= 285) were treated in shared care with contractual adherence to a diabetes centre receiving two or more daily injections (table 1 & 2).

As shown in figure 1, a clear correlation was seen between diabetes duration and intensification of therapy. Less than 10% of the patients with disease duration less than 5 years received insulin vs. 46% of those with duration of more than ten years. This disease evolution is typically accompanied by a deterioration of glycemic control, as expressed by HbA1c levels, and an increase of cardiovascular complications (Table 1 and 3).

Data reveal some clinical inertia as 17% of the patients on OADs had HbA1c-levels ≥ 8% and even 10% (N=169) had levels ≥ 8.5%. In the latter group, diabetes duration was significantly higher than in those patients with HbA1c< 8.5% (6.7 years vs. 6.1 years, p<0.0001 using a Poisson mixed model). In addition, insulin treated patients adhering to diabetes centre had better glycemic control than those primarily treated by the GP (table 2).

Subgroup analysis according to the type of hypoglycemic treatment regimen, showed that more intensive glucose-lowering treatment (insulin > 0ADs > no drugs) was associated with achieving more targets (Table 1). LDL-C and DBP levels were lower whereas statin and aspirin use was more prevalent (Table 2). Of interest, when analyzing insulin-treated patients according to the site where diabetes was primarily managed (GP vs. diabetes centre), the effect on achieving targets was correlated to the site rather than to insulin-treatment itself being present (Table 2). These results were confirmed by a multiple regression model (Table 3): HbA1c clearly deteriorated with duration and complexity of disease. In insulin treated patients, HbA1c and LDL-C were lowest in patients followed up in specialized diabetes centres.

Discussion

The present study reports the status of care in patients with Type 2 Diabetes, generally treated in a primary care setting in Belgium and is reflective of the situation of global Type 2 Diabetes care in many industrialized countries, with good health care facilities, but with loosely organized primary care and the absence of strict care management. The achievement of targets was very diverse, with HbA1c classically being one of the hardest to control. Also in our study, only half of the patients reached the goal of HbA1c<7%, a result comparable and even slightly better than those in previous studies in other countries: United States (50% reaching the ADA-target in the NHANES (15) study) ; Canada (Mean HbA1c 7.3 with 51% reaching the ADA-target) ; Australia (52% reaching the ADA target (16)) ; Germany (Mean HbA1c 7.1% and 6.9% in two different studies (17;18)) ; Italy (Mean Hba1c 7.2% with 52% reaching the ADA-target (19)) and Ireland (Mean HbA1c 7.1%) (20). This result may be the consequence of the Belgian system, where more complex patients have access to a reimbursement system for self monitoring materials and education in specialized diabetes centres. Still, also in our population, we recognize clearly the deterioration of glycemic control and need for additional hypoglycemic interventions with progressing duration of the disease. Indeed, HbA1c levels were worse in the insulin treated patients, reflecting increasing complexity of the disease. However, when these patients were followed in shared care with a specialized diabetes centre, the levels of HbA1c were lower than when the GP took care of the patient without help of the specialist, indicating a beneficial effect. This beneficial effect of shared care was also noticeable on the other parameters, such as LDL-cholesterol, being

lower in patients attending not only GP clinics, but also the specialized diabetes clinics in the centres.

Some study limitations have to be mentioned. First, all primary care physicians participated in the study on a voluntary basis, reflecting the performance of a selected and motivated cohort of physicians operating in a well-defined area. They present other characteristics than the general physician population: more female, younger, more group practices, higher computerization level. This selection bias could express an overestimation of the global quality of diabetes care in primary care and an underestimation of the practice diabetes prevalence. Second, in terms of characteristics of the patient population, only a limited number of different races and socio-economically deprived subpopulations live in the studied area. As a result, the data presented in this paper could again be more favourable compared to data of the overall population. A third limitation of practice-based research refers to the reliability of medical data gathering. In this large field study some of the data were not double-checked, e.g. laboratory data were collected from different laboratories and no external control was performed on blood pressure measurement. The absence of patient registries is an important weakness in the Belgian health care system with consequences on the present study. Despite considerable efforts to include as many patients with diabetes as possible, control with a laboratory based data monitor shows that only about 80% of the patients with diabetes have been included in the study again resulting in an underestimation of the diabetes prevalence.

Our data also reflect the progressive nature of the disease and the clinical inertia in intensifying hypoglycemic treatments, as too many uncontrolled patients on OADs are not moved to insulin therapy timely. Insulin therapy onset is often feared by patients and considered as a landmark event in the personal history, an event that patients prefer to postpone as much as possible (21). In addition to the classical barriers to initiating insulin in patients with Type 2 Diabetes, initiation of insulin in the setting of Belgium is particularly counteracted by the dichotomy between primary care and endocrinologists, installed by the reimbursement system, limiting reimbursement of diabetes education and self home blood glucose monitoring materials to specialized diabetes centres. This skewed reimbursement prevents many GPs from timely initiating insulin, in an already insulin-hostile population (22). Of interest is the difference in HbA1c levels in insulin-treated patients with main

follow-up mainly in primary care and patients primarily followed in specialist diabetes centres. In the latter patients, not only the age adjusted HbA1c values were lower. Patients also were more at target for other essential metabolic targets like LDL-C and for the intake of guardian drugs such as statin therapy. This can be the reflection of a greater focus on the single disease of diabetes by the endocrinologists and thus a better adherence to guidelines. We believe however that the existence of an integrated and structured care, with planned visits, structured programs and the presence of staff members including diabetes educators is a crucial contributor to the better level of care. Many studies indicate that the introduction of structured care and diabetes nurse educators clearly improves the quality of diabetes care and overall metabolic control (23-28)

These questions are particularly important and yet controversial for the diabetes care in patients with old age. In our study, more than 40% of the population was older than 70 years and 14% was even older than 80 years. Elderly people represent a heterogeneous subpopulation with a continuum of patients from those in very good shape (despite diabetes) to very ill, frail and disabled patients (29) presenting with co-morbidity and geriatric syndromes like cognitive impairment, functional disability, chronic pain, falls,… Those patients are ideally treated in the primary care because of their functional disability. The prevalence of Mild Cognitive Impairment e.g. can be estimated at 15% in the general population over 75 years. The prevalence of cognitive impairment may be higher in the diabetes population (30) and is associated with the severity and duration of hyperglycemia and with hypertension (30-32). This finding could be an extra stimulus to sharpen diabetes control (33) but the syndrome interferes with therapy compliance (34-36) and thus influences diabetes related outcomes. Moreover, elderly patients are particularly sensitive to the adverse effects of drugs and polypharmacy like hypoglycemia and falls, putting constraints on the classic diabetes treatment. As such, strict adherence to guidelines for younger patients could be deleterious for the frail elderly (37) who are in need for specific geriatric guidelines (38). As these guidelines accentuate, treatment should be holistic, targeting all important aspects of the geriatric patients with priorities in the treatment scheme. (39) Thus, diabetes related targets should be individually adapted to the frail patients with special attention to avoidance of side effects (33). Especially hypoglycemia is an important topic in the elderly with recent studies (40) clearly

indicating that hypoglycemia may be a contributing factor to morbidity and mortality in older patients. Therefore the use of new drugs that are able to reduce glycemia without hypoglycemia should be considered in these patients (41).

Globally, our results suggest that patients with Type 2 Diabetes, exposed to shared care between GPs and specialized care obtain better results in glycemia, blood pressure, lipid and pharmacological treatment targets. International literature often compares primary vs. specialized care. Most of the studies show that specialized care obtains better results than primary care either for process or for intermediary outcome variables without necessarily finding an impact on mortality (42). These studies however tend to oppose the two care levels and may compare patient groups that are not comparable. Our study shows the complementarities between the two care levels which means that the end stage patients necessitating the most complex treatment are primarily managed by specialized care in shared care with the GP, while the majority of patients are treated at primary care level. However, this study also shows that quality of care could be improved in those patients primarily treated by the GPs. Structured care is yet lacking in many countries with a majority of single handed practices. At present, no guidance is given to the organization of diabetes follow-up in primary care. Therefore, it will be of interest to investigate whether a better integration of the different care levels and the introduction in the GP setting of the more structured, consensus and guideline-based approach present in diabetes centres will be able to improve the quality of care for patients with Type 2 Diabetes with respect to achieving outcome and process parameters.

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Table 1. Patient characteristics and quality of care according to the hypoglycemic treatment regimen.

Parameter/target	*All*	*No drugs*	*OAD*	*Insulin*	*p*
N	2495	314	1699	482	
Mean age (years)	68 ±12	66±13	68±11	69±12	0.0003
Mean diabetes duration (years)	7.2±7.0	3.1±4.0	6.1±5.4	13.8±9.1	<0.0001
Female gender	51%	50%	50%	56%	0.0488
HbA1c < 7%	54%	76%	56%	33%	<0.0001
SBP ≤ 130 mm Hg	50%	46%	50%	50%	NS
LDL-C < 100 mg/dl	42%	30%	40%	57%	<0.0001
HbA1c (%)	7.1±1.3.	6.8±1.2	7.1±1.2	7.6±1.4	<0.0001
SBP (mm Hg)	136±16	137±16	136±16	135±16	NS
DBP (mm Hg)	79±10	81±12	80±10	77±9	<0.0001
LDL-C (mg/dl)	108 ±34	118±36	109±32	98±36	<0.0001
BMI	29.6 ±5.3	29.6±4.9	29.5±5.1	30.1±5.9	NS
Statin	39%	37%	37%	50%	<0.0001
Aspirin/clopidogrel	40%	31%	37%	57%	<0.0001
History of CVD	27%	25%	24%	43%	<0.0001

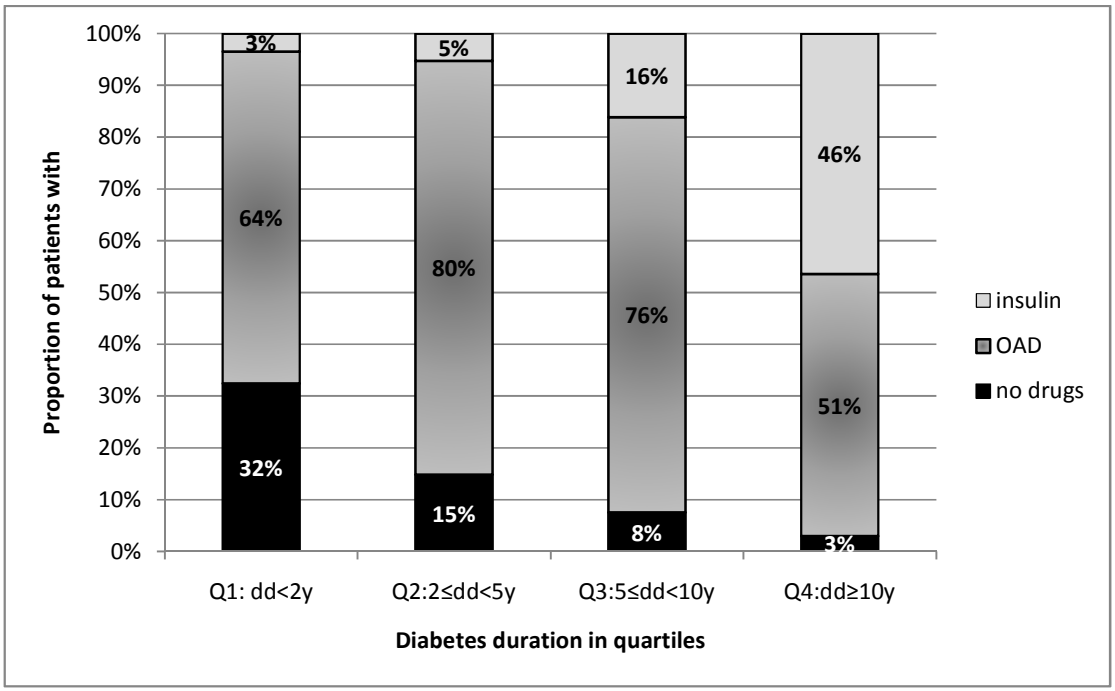
Table 2. Patient outcome parameters and CV risk lowering treatments in insulin-treated patients by setting of care.

Parameter/target	*Insulin GP*	*Insulin-centre*	*p*
N	197	285	
Mean age	73±12	66±12	<0.001
Mean diabetes duration	13.4±8.6	14.1±9.1	NS
Female gender	59%	54%	NS
HbA1c < 7%	31%	35%	NS
SBP ≤ 130 mm Hg	49%	50%	NS
LDL-C < 100 mg/dl	43%	67%	<0.001
HbA1c (%)	7.8±1.5	7.5±1.2	0.038
SBP (mm Hg)	135±16	135±16	NS
DBP (mm Hg)	77.4±8.5	77.6±8.6	NS
LDL-C (mg/dl)	111±37	90±34	<0.001
Statin	33%	66%	<0.001
Aspirin/clopidogrel	51%	60%	NS
History of CVD	40%	45%	NS

Table 3: Multiple regression analyses of HbA1c, SBP and LDL-C.

	HbA1c (%) N=1602		*SBP (mm Hg) N= 1622*		*LDL (mg/dl) N= 1442*	
Effect	Estimate (SE)	p	Estimate (SE)	p	Estimate (SE)	p
Diabetes duration/year increase	0.020 (0.005)	<0.0001	−0.04 (0.07)	0.5259	−0.24 (0.6)	0.1182
Insulin-GP vs. OADs	0.740 (0.117)	<0.0001	-1.82 (1.60)	0.2557	6.6 (3.7)	0.07
OADs vs. no drugs	0.204 (0.092)	0.02644	−1.31 (1.24)	0.2896	−7.5 (2.7)	0.0059
Insulin GP vs. Insulin centre	−0.445 (0.139)	<0.001	2.07 (1.90)	0.2755	21.5 (4.3)	<0.0001

Figure 1: Association between diabetes duration and hypoglycemic treatment group.



Legend: Note that with increasing diabetes duration, hypoglycemic treatment becomes more intense.

Chapter 2: Start Improving the Quality of Care for Patients with Type 2 Diabetes through a General Practice Support Program: a Cluster Randomized Trial.

*G. Goderis, L. Borgermans, R. Grol, C. Van Den Broeke, B. Boland, G. Verbeke, A. Carbonez, C. Mathieu, J. Heyrman. Start improving the quality of care for people with Type 2 Diabetes through a general practice support program: a cluster randomized trial. Diabetes Res.Clin.Pract. 2010;**88**:56-64.*

ABSTRACT

Aims: To evaluate the effectiveness of a two-arm Quality Improvement Program (QIP) in support of General Practice with limited tradition in chronic care on Type 2 Diabetes patient outcomes.

Methods: During 18 months, we performed a cluster randomized trial with randomization of General Practitioners (GP). The Usual QIP (UQIP: 53 GPs, 918 patients) merged standard interventions including evidence-based treatment protocol, annual benchmarking, postgraduate education, case-coaching for GPs and patient education. The Advanced QIP (AQIP: 67 GPs, 1577 patients) introduced additional interventions focusing on intensified follow-up, shared care and patient behavioural changes. Main outcomes were HbA1c, Systolic Blood Pressure (SBP), and Low Density Lipoprotein Cholesterol (LDL-C), analyzed by Generalized Estimating Equations and linear mixed models.

Results: In UQIP, endpoints improved significantly after intervention: HbA1c -0.4%, CI95%[-0.4;-0. 3]; SBP -3 mmHg, CI95%[-4; -1]; LDL-C -13 mg/dl, CI95%[-15; -11]. In AQIP, there were no significant better improvements in outcomes: HbA1c -0.4%, CI95%[-0.4;-0.3]; SBP -4 mmHg, CI95%[-5; -2]; LDL-C -14 mg / dl, CI95%[-15; -11].

Conclusions: A multifaceted program merging standard interventions in support of General Practice induced substantial improvements in the quality of diabetes care. Intensified follow-up in AQIP with focus on shared care and patient behaviour changes did not yield additional benefit.

Key words: Type 2 Diabetes Mellitus, Quality of Healthcare, Primary Care, Implementation Program

Introduction

Type 2 Diabetes Mellitus (T2DM) leads to severe micro- and macrovascular complications, resulting in increased morbidity, but particularly in a two- to six-fold increased cardiovascular risk (1;2). Clinical evidence suggests that aggressive, timely, and multi-factorial interventions (3) aimed at controlling risk factors such as high blood pressure(4), blood lipids (5;6), and glycemia (7;8) can reduce T2DM complications. General Practice plays a key role in the management of this disease, but the field suffers from clinical inertia. This inertia is characterized by insufficient adherence to guidelines aimed at reducing measures of glycemia and cardiovascular risk factors to target values (9). Additional barriers to clinical improvement are the absence of integrated mechanisms between primary and secondary care, and insufficient patient involvement during treatment (10).

High quality Type 2 Diabetes care is a complex matter. All over the world, Quality Improvement Programs (QIPs) have been used to improve diabetes care (11-14). Many intervention programs do not succeed, or yield only small improvements (15-17). Multifaceted interventions are more likely to exert positive effects than single interventions (18). Nevertheless, the variety in QIP design and associated outcomes undermines clear conclusions about optimal program models, or how intensively the physician and patient population should be followed (19).

Before introducing a nation-wide QIP based on the principles of the Chronic Care Model, the Belgian government ordered a cluster randomized trial in the primary care setting. The mainly demand driven organization of care in Belgium makes the situation comparable to settings in the USA, France, Italy or Canada (10). We compared the effects of “Advanced Quality Improvement Program” (AQIP) with “Usual Quality Improvement Program” (UQIP) on measured outcomes of care success in T2DM patients. As they are valuable predictors of morbidity and mortality, we chose the following measures of care success: glycated hemoglobin (HbA1c), Systolic Blood Pressure (SBP), and LDL-Cholesterol (LDL-C). Using a set of standard interventions merged into a multifaceted general practice support program, UQIP implemented a treatment protocol whereby GPs aimed for evidence-based target values in patients. These target values were set according to the standards of the American Diabetes

Association (ADA), and are defined as: HbA1c of 7%, SBP of 130 mm Hg, and an LDL-C of 100 mg / dl. On top of UQIP, AQIP implemented a more elaborate and cost-intensive program with 3 supplementary focuses: 1) intensified, three-monthly follow-up of the GPs; 2) active stimulation to share care, and 3) additional facilitation of patient behaviour changes, such as lifestyle habits and treatment compliance.

Subjects, Materials and Methods

Study design

The Belgian National Institute for Health and Disability Insurance (NIHDI) sponsored this project, in an effort to examine the usefulness and feasibility of a nation-wide implementation. To this end, NIHDI stipulated there be recruitment of at least 33% of available physicians in the region. Similar to other complex intervention evaluations (20), we organized an open pragmatic before / after study, with randomization of General Practices in two intervention arms, AQIP and UQIP. Patients were clustered around their General Practitioner. This cluster design was necessary because randomization was performed on a practice level, the intervention mainly happened on the physician level, but a large part of the data was analyzed at the patient level. Patient data were gathered prospectively by volunteer GPs who worked in regions surrounding the University Hospital Gasthuisberg in Leuven. All 336 GPs invited to participate were asked to register all their known T2DM patients. After the initial recruitment phase, a researcher blinded to the study design used computer-generated numbers to randomly assign GPs. Randomization was stratified by practice size in single working GPs, duo practices and group practices with three or more GPs.

Despite the imposed sample size, we performed a power calculation (21). With a significance level of 0.05 and assumed Intra Cluster Coefficient of 0.1, we calculated that 114 clusters with a cluster size of 20 gave 80% power to detect between AQIP and UQIP a 10% in the absolute difference in the proportion of patients achieving a 10% improvement in the primary biochemical endpoints.

All patients were blinded to the study design, but physicians were not, as they were involved in the execution of the programs. Baseline data were designated T0, and collected from January to July 2005. For the development of data in

paper charts, we asked GPs to perform a complete examination, including a blood analysis, on the first visit of T0. Endpoint data were designated T1, and collected from May to November 2006. T2DM diagnosis was defined in accordance with the 2003 ADA criteria (22). The project was approved by the local ethics committee and registered as # NTR1369, with publication of the study protocol (23).

Interventions with physicians and patients

The intervention period was January 2005 to November 2006. As explained in the study protocol, GPs of both arms received the same basic support program of interventions (UQIP) that was based on the Chronic Care Model and theoretical frameworks for change management (see also addendum) (24-26). These interventions represent standard requirements for what is considered quality diabetes care (27). The aim of UQIP was to implement the Evidence Based guidelines recommending a global, target-driven and intensified treatment of Type 2 Diabetes. The interventions of UQIP were available for all participating GPs and patients. However, UQIP was proposed as a service: GPs and patients of the UQIP arm were free to choose their level of participation in all these offered services. Physicians received €60 for each included patient and an evidence-based treatment protocol based on ADA-guidelines and elaborated in consensus with local GPs and endocrinologists. According to this protocol, GPs received the main responsibility for the follow-up of their patients. The protocol recommended regular follow-up of the patients with attention to all important parameters (biological risk factors and early signs of complications) and recommended global treatment that should be intensified whenever the targets were not reached. Targets were set at 7% for HbA1c, 130 mm Hg for SBP and 100 mg/dl for LDL-C. UQIP offered two postgraduate educational sessions. The first explained the Evidence-based treatment protocol in detail. The second explained the principles of insulin treatment of T2DM patients in general practice. All GPs could appeal on case-coaching by an endocrinologist by phone or by email if they encountered problems to treat their patients. Printed benchmarking feedback on HbA1c, Blood Lipids, Blood Pressure, BMI, statin and aspirin prescription was provided at the beginning of the study and one year later.

At patient level, we facilitated patient education via an Interdisciplinary Diabetes Care Team (IDCT) that could be counselled upon referral by the GP. This team included a nurse educator, a dietician and a general internist with interest in diabetes. The program focused on disease insight, nutrition, physical exercise and medical treatment compliance. Patients with insulin therapy were educated how to self-manage insulin therapy. The educational initiatives were free of charge for all included patients.

For the AQIP arm, we introduced additional interventions on top of the UQIP. At GP-level, AQIP provided a three-monthly, intensified follow-up, actively stimulated patient referral to the educational initiatives and paid special attention to patient-centred communication. All GPs of the AQIP arm received a detailed Shared Care Protocol defining the responsibilities of all partners combined with intensified specific postgraduate education, three-monthly benchmarking and three-monthly feedback on each individual included patient. Regular reminders actively encouraged GPs to refer all their patients not reaching the targets. Other reminders encouraged GPs to collaborate with existing community campaigns on smoking cessation and physical activity. For those purposes, all GPs of the AQIP arm received 4 extra emails, 2 written letters and 3 extra phone calls. Two supplementary postgraduate sessions and peer discussions on patient-centred counselling and management of lifestyle habits explained the principles and practice of the Transtheoretical Model of Change (TTM) (28). Finally, GPs were invited by telephone to participate in the joint meetings with IDCT and endocrinologists when case discussions concerned one of their patients.

For patients of the AQIP-arm, the IDCT was moreover reinforced with a health psychologist and a diabetes educator who delivered diabetes education at the patients' home. Referral to the health psychologist was recommended for all patients with difficulties to maintain healthy lifestyle habits. The counselling techniques included extended motivational interviewing based on the Trans Theoretical Model of change.

Finally, AQIP also offered the possibility of organized group educational sessions for patients and family members. These group sessions were organized by the project team and presented by the IDCT in collaboration with the GPs. Specifically, we organized the distribution of printed educational brochures,

pedometers and Home Blood Glucose Material (HBGM), which are not typically reimbursed in Belgium for patients on Oral Antidiabetic Drugs, or followed up solely by primary care.

The preparation and organization of the project were implemented by a team that included two senior researchers (one GP and one endocrinologist), two junior researchers (one GP and one nurse educator) and one 'program manager'. The program manager played a key role in the implementation of both UQIP and AQIP. She managed all logistics needed to implement the aforementioned interventions and organized the communication with and between GPs, endocrinologists and the IDCT. She particularly paid attention to motivate the participating GPs and to answer all their questions related to the project. Benchmarking feedback and statistical analyses were performed by a professional statistical unit led by a senior researcher in statistics. Both teams worked in close collaboration.

Endpoints and statistical analysis

Differences in physician characteristics were tested using a t-test for continuous and a χ^2-test for dichotomous outcomes. Primary endpoints were defined as improvements in HbA1c, SBP and LDL-C measures, and secondary endpoints were defined as improvements in HDL-C, Total Cholesterol, Diastolic Blood Pressure (DBP), weight, smoking status, statin and anti-platelet therapy efficacy measures. Endpoints were analyzed according to the intention-to-treat principle. Means were reported for continuous variables, and proportions were reported for dichotomous variables. To compare patient characteristics between AQIP and UQIP, the Generalized Estimating Equations (GEE) approach of Liang and Zeger (29) was used, taking into account the clustered nature of data within physicians (SAS, version 9). For binary variables, we used the exponential inverse transformation to obtain the 95% confidence interval for the odds ratio. Since not all variables were available for all patients, case-wise deletion was used.

Subgroup analyses using linear mixed models with random patient effect compared the change of primary endpoints and the initiation of insulin, blood pressure lowering, and statin therapies, according to various cut-off values

corresponding to international accepted thresholds for control of the disease (table 3). Dichotomous outcomes were analyzed with logistic mixed models. Further on, linear mixed models with subject-specific intercepts and slopes tested whether subject-specific changes were related to the initial level of the outcomes. This complex statistical analysis was performed because it allows for eliminating the 'regression to the mean effect' in significance testing on the observed changes. HbA1c values were transformed logarithmically to meet the parametric assumptions of the statistical models.

Cost estimation

To calculate the investment cost of services administered in both UQIP and AQIP, we gathered detailed data about staff salaries, payments to practices, postgraduate education fees, and logistics throughout the study.

Results

Physician profile, participant flow, and program participation

A total of 142 physicians from 90 practices agreed to participate and were randomized (Figure 1). Within the first 30 days, 22 physicians dropped out (UQIP = 18, AQIP = 4, $p < 0.001$). Thus, only 120 physicians (36% of those available, 67 AQIP vs. 53 UQIP) registered baseline data. During the study there was negligible drop-out (AQIP = 0 and UQIP = 2, NS). We observed small differences in physicians' characteristics for age (AQIP 46 vs. UQIP 43 years), the mean number of patient contacts (AQIP 97 vs. UQIP 92 per week), the proportion of female physicians (AQIP 40% vs. UQIP 51%) and the proportion of physicians working in solo practices (AQIP 37% vs. UQIP 40%) and duo practices (AQIP 36% vs. UQIP 26%). Mean follow-up was 18 months with a range from 12 to 23 months.

Physician attendance at common educational meetings was 76% in AQIP and 70% in UQIP ($p = 0.173$). AQIP physicians referred significantly more patients to the IDCT than UQIP physicians (AQIP: 223 (14.4%) vs. UQIP: 86 (9.6%), $p = 0.03$) with in total 178 (7.1%) referred patients to the dietician, 145 (5.8%) to the educator and 108 (4.3%) to the general internist. The proportion of GPs who monthly referred to the diabetes educator increased during the project from 5% in

the first month (January 2005) to 16% in July 2006." Patients referred to the IDCT showed higher baseline HbA1c values than patients who were not referred (7.8±1.6% vs. 7.1±1.2%, p< 0.0001). At the end of the intervention, 596 patients (27% of the total population, 26% AQIP and 29% UQIP, p=0.12) did not reach the HbA1c target and have not been referred to the IDCT.

The use of additional interventions in the AQIP-arm was as follows. Physician attendance at extra postgraduate sessions specific to AQIP was 49%. The 'travelling' educator was consulted by 40 patients (2.5%) and the health psychologist by 18 patients (1.1%). Seven group educational meetings were organized, with 310 participants referred by 14 physicians, 126 patients received printed educational brochures, 201 received pedometers and 107 received HBGM.

Patient outcomes

The study included 2495 patients (AQIP 1577, UQIP 918), representing 80% of the patients with diabetes according to a control with a laboratory based data monitor. There were no significant differences between baseline patient characteristics of the two intervention arms (Table 1) with only about half of patients reaching individual outcome targets (Figure 2). In AQIP, the proportion of patients achieving a 10% improvement in the value of HbA1c, LDL-C or SBP was 63%, CI95% [60-66]. As shown in table 2, all three primary endpoints improved significantly after the intervention. HbA1c was reduced 0.4%, CI95%[-0.4;-0.3], SBP 4 mmHg, CI95%[-5; -2], LDL-C 14 mg / dl, CI95%[-15; -11]. However, there were no significant differences in outcomes between AQIP and UQIP. In UQIP, the proportion of patients achieving a 10% improvement in the value of HbA1c, LDL-C or SBP was also 63%, CI95%[59-67]. HbA1c reduced by 0.4%, CI95%[-0.4;-0. 3], SBP by 3 mmHg, CI95%[-4; -1], LDL-C by 13 mg/dl, CI95%[-15; -11]. Only anti-platelet therapy use and evidence of physical exercise were significantly higher in AQIP (table 2).

Table 3 shows the change of primary endpoints as well as associated treatment changes, according to different baseline values. Data are presented for all patients because no significant differences were found between AQIP and

UQIP. For all three endpoints, patients not in good control at baseline showed significant higher change compared to patients that were in control at baseline and higher initial values were associated with increased treatment intensification. For example, the mean change in HbA1c is -1.6%±1.28% for those patients with initial levels >8%. Initiation of insulin therapy in this subgroup amounts to 18% of the patients not receiving insulin therapy at baseline. In patients with initial HbA1c-levels between 7% and 8%, the mean change is -0.4% ± 0.80% with insulin initiation of 6%. We did not observe any change in the mean HbA1c-level of patients who were in control at baseline and insulin was initiated in only 1.5% of this subgroup.

The correlation between the patient-specific intercepts (baseline values) and slopes of each primary endpoint was statistically significant ($p < 0.001$), with the following correlation coefficients: log (HbA1c) = -0.514; SBP = -0.447; LDL-C = -0.331. These results show that the changes in outcome were significantly associated with their initial values. Thus improvement was more commonly observed in the patients with the worst initial conditions.

Costs

The annual investment cost of UQIP was €226156 or €164 ($210) per patient. Of this cost, 61% was spent on staff salaries, 28% on payment to practices, 10% on equipments and logistics, and 1% on postgraduate education. The annual investment cost of the AQIP amounted to €481990 ($616706) or €204 ($261) per patient. Of this cost, 70% was spent to staff salaries, 21% on payment to practices, 7% to equipments and logistics and 3% on postgraduate education.

Discussion

Previous research has shown that shared care improves both the delivery of diabetes care (30) and patient outcomes (31), whereas increased treatment adherence, weight loss and regular physical activity have a beneficial effect on the control of glycemia, blood pressure and blood lipids (32-34). The present study investigated whether improved patient outcomes could be achieved with a basic support program (UQIP), and whether intensified support of GPs and patients in the AQIP arm paying special attention to shared care, patient

compliance and adherence to lifestyle change would further improve outcomes in T2DM patients achieved by the UQIP.

Both programs were implemented in a 'traditional' Western European primary care setting that is mainly focused on reactive, demand driven care with Fee-for-Service payment (35). Most GPs work in solo practices or small duo practices without additional logistic or nursing staff. Diabetes patient registries, planned diabetes consultations and practice quality evaluation are not available in primary care. Shared care is loosely organized since GPs cannot rely on structured assistance of dieticians or diabetes educators in their practice. Moreover there is no formal shared care collaboration between primary and specialist care. This situation is not specific to Belgium. Many other countries like France, Italy, Austria, Canada and some settings in the USA face a similar situation. Therefore, our results may be applicable to those health care settings.

The baseline data of this study showed that there is room for improvement in the major treatment targets and confirmed the problem of clinical inertia (36). After 18 months of intervention, all primary and most secondary endpoints improved in both intervention arms. Notable is the enhanced prescription of guardian drugs like statin and anti-platelet therapy. Moreover, as table 3 shows, intensification of insulin, blood pressure and statin treatment was significantly higher in patients who were not in good control at baseline and was associated with better improvement of respectively HbA1c, SBP and LDL-C. These findings demonstrate the effect of the intervention on adherence to the guidelines recommending target-driven and global cardiovascular treatment on top of glycemic control (37-39).

However, additional incentives in AQIP did not result in major improvements over UQIP. We only observed a significant additional impact on two secondary endpoints (physical exercise and anti-platelet treatment), with no additional impact on primary endpoints.

One of the interventions to facilitate patient behaviour change was a training course on the Trans Theoretical Model of change. Despite a lack of consistent evidence for its efficacy (40-42), the TTM provides a widely accepted framework for health care providers to develop lifestyle interventions focused on the stage of

readiness to change (43). We hypothesized that the combined action of this training with additional patient empowerment tools and intensified patient referral to the IDCT could induce substantial changes in patient behaviour, and additional improvements in the primary outcomes. We indeed observed a higher referral rate to the IDCT in the AQIP arm compared to the UQIP arm, but we did not observe any differences in primary outcome improvements between the two intervention arms. Previous research has shown that patient education and interdisciplinary diabetes care teams have a positive effect on patient outcomes, especially on HbA1c (16;44). These observations are somewhat contradictory to our findings. However, the differences in referral rates to the IDCT between UQIP and AQIP and the use of additional empowerment tools may not have been large enough to induce a significant effect on the primary outcomes. A second possible explanation is that the effect of the additional interventions on the primary outcomes may have been compensated by other interventions in UQIP stimulating the GPs to assure a stricter medical follow-up by own means. This hypothesis particularly questions the exact positioning of interdisciplinary diabetes care teams as a part of a multifaceted QIP in General Practice. Further detailed analysis on the effect of the IDCT referral on patient outcomes is needed to clarify this issue and will be reported in a separate article.

The relative low referral rates of patients to the IDCT (AQIP 14.4% vs. UQIP 9.6%) are in part the reflection of the treatment protocol that recommended GPs to refer patients whenever the treatment targets were not reached despite own efforts. GPs adhered at least partly to this recommendation since they mostly referred patients with higher HbA1c-levels. However, 27% of the included population, not reaching the HbA1c target at the end of the study, should have been referred to the IDCT, but were not. In a nested qualitative study, we interviewed 20 participating GPs and the results of this study will be separately discussed. When confronted to their referral behaviour, most GPs mentioned that some patients refused to be referred to the IDCT while some GPs admitted not being convinced about the added value of patient education by educators or dieticians. Moreover as shown by the increasing GP referral rates during the project, behaviour change takes time as new attitudes must be consolidated into routine practice. These findings confirm the difficulties of implementing new and

innovative interventions in an existing health care system. Besides, interventions that merely focus on GPs are mostly inadequate if not accompanied by interventions that focus on patients' behaviour. Thus, further research is needed to define all barriers and facilitators to shared care between patients, GPs and diabetes educators in primary care.

Regarding the beneficial effect of UQIP alone, it is not possible to draw a formal conclusion, because a pure randomized control group without any intervention was not included in this study. We deemed it impossible to introduce such a control group, because physicians perceived registering data on paper charts as an important additional workload, and expected a benefit or at least an active support for doing this. However, the results of our trial are in line with the increasing evidence for the efficacy of those 'standard' interventions on clinical inertia (15;45), that can be considered as standard requirements for high quality care (46-48).

However, in a post-hoc analysis, we compared the change of the primary outcomes between a random sample of the intervention population and a matched subgroup of patients with T2DM from the «INTEGO» Registry Network (IRN). In this network, we organize a rigorous follow-up of bio-clinical data out of 56 sentinel practices (80 physicians) spread throughout Belgium (49). It is designed to reflect nation-wide trends in General Practice. Matching was performed on age, sex, diabetes duration and baseline HbA1c-level. We succeeded in matching 587 intervention patients (300 AQIP, 287 UQIP) with 507 patients of the IRN. Baseline values of the matched IRN subgroup were not statistically different from those of the intervention group for age, female gender, diabetes duration, HbA1c, SBP and LDL-C. Still, compared to the matched IRN subgroups, the change in both intervention arms was significantly better for HbA1c (UQIP -0.4% vs. IRN -0.1%, $p < 0.001$) and LDL-C (UQIP -16 mg / dl vs. IRN -8 mg / dl, $p = 0.021$), but not for SBP (UQIP -3 mmHg vs. IRN -3 mm Hg, $p=0.55$). These data indicate that UQIP yield a beneficial effect on two of the three primary endpoints. We also estimated the risk reduction in the combined ten-year risk of Coronary Heart Disease (CHD) and stroke. We introduced the values for HbA1c, blood pressure and blood lipids, from both the UQIP arm and the matched IRN subgroup in the UKPDS risk engine® spreadsheet, a validated

risk estimation model (50;51). The estimated baseline risk was 29.0% (UQIP) and 29.8% (IRN). The Relative Risk Reduction in favour of the UQIP was estimated at 13% (CI95% [5-20]), the "Number needed to treat" at 26 (CI95% = [16-63]).

There were several weaknesses of the present study. First, important efforts were required to motivate GPs for the project, resulting in a global enhancement of diabetes awareness throughout the region. Secondly, despite the motivation of the GPs, we observed a significant difference in initial drop-out rate between the UQIP and AQIP-assigned GPs, which may indicate that being assigned to AQIP motivated more physicians to pay closer attention to T2DM care. However, probably the most motivated GPs remained in the UQIP arm, with possible effects on the final outcomes. Thirdly, some of the additional, interventions of the AQIP arm were only used by a small number of participants. This is particularly true for the health psychologist counselling, which was only used by 18 patients.

In conclusion, UQIP positively motivated a large cohort of GPs to take a central responsibility in diabetes care and compiled a basic set of interventions in support of General Practice: the offer of a clear treatment protocol supported by tailored postgraduate education for GPs, case-coaching by an endocrinologist, annual benchmarking feedback and the opportunity of referring patients for diabetes education free of charge. These five basic interventions, merged to a multifaceted program substantially improved overall quality of care and the major diabetes related patient outcomes. The average investment costs of UQIP amounted to €164 ($210) per patient, a rather modest amount compared to the total annual diabetes-related medical costs estimated at €1207 (52). Additional interventions in three areas - a more intense, three monthly follow-up of GPs, actively stimulated shared with an interdisciplinary diabetes care team care and additional facilitation of patient behaviour changes - did not add substantial benefit, despite an incremental annual cost of €40 per patient.

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Table 1. Patient data at baseline (T0)

	AQIP N=1577 Mean ± SD % [CI95%]	UQIP N=918 Mean ± SD % [CI95%]	p*
Age (yrs)	68 ± 12	68 ± 12	0.536
Diabetes duration (yrs)	7.2 ± 6.9	7.2 ± 7.3	0.929
% female	51% [51-57]	53% [49-58]	0.443
HbA1c (%)	7.1 ± 1.3	7.2 ± 1.3	0.7803
SBP (mm Hg)	136 ± 15	137 ± 18	0.3622
DBP (mm Hg)	80 ± 9	80 ± 9	0.8135
T-C (mg / dl)	191 ± 40	194 ± 41	0.1151
LDL-C (mg / dl)	107 ± 33	111 ± 34	0.0648
HDL-C (mg / dl)	54 ± 16	53 ± 15	0.5936
BMI (kg / m^2)	29·6 ± 5.2	29·6 ± 5.3	0.9515
Smoking (%)	14 [11-16]	16 [13-20]	0.1828
Regular Exercise (%)†	53 [48-57]	53 [47-58]	0.9835
Aspirin / Clopidogrel (%)	41 [37-45]	36 [31-41]	0.1335
Statin treatment (%)	41 [37-45]	38 [33-42]	0.2361

UQIP= Usual Quality Improvement Program (53 physicians, 32 practices, 918 patients)
AQIP = Advanced Quality Improvement Program (67 physicians, 42 practices, 1577 patients)
* $p < 0.05$ for the baseline difference between the UQIP and AQIP, tested with a GEE model. Effects were adjusted for the clustering of patients within practices.
†Regular Physical Exercise: light to moderate exercise adapted to the patient's situation (e.g. walking, exercises at home) for least 3 times a week during 20 minutes.

Table 2. Changes in clinical and biochemical parameters by end of study in UQIP and AQIP arms (T1)

	AQIP N=1577			UQIP N=918			
Continuous outcomes	Mean Δ		CI95%	Mean Δ*		CI95%	p‡
HbA1c (%)	-0.4		[-0.4;-0.3]	-0.4		[-0.4;-0.3]	0.660
SBP (mm Hg)	-4		[-5;-3]	-3		[-4;-1]	0.060
DBP (mm Hg)	-2		[-3;-2]	-2		[-3;-1]	0.718
T-C (mg / dl)	-17		[-19;-15]	-14		[-17;-12]	0.204
LDL-C (mg / dl)	-14		[-15;-12]	-13		[-15;-11]	0.634
HDL-C (mg / dl)	+1		[0;2]	+1		[1;2]	0.254
BMI (kg / m²)	-0·4		[-0.5;-0.3]		-0.4	[-0.6;-0.3]	0.792
Dichotomous outcomes	Δ (T1-T0)	OR* [T1/T0]	CI95% OR [T1/10]	Δ*	OR* [T1/T0]	CI95% OR [T1/10]	p‡
Smoking (%)	-2	0.85	[0.76; 0.97]	-4	0.69	[0.60;0.80]	0.051
Physical Exercise (%)	+8	1.46	[1.31; 1.63]	+1	1.08	[0.94; 1.24]	0.001
Anti-platelet therapy (%)	+21	2.32	[2.08; 2.59]	+12	1.64	[1.42; 1.89]	<0.001
Statin treatment (%)	+14	1.80	[1.63; 1.99]	+11	1.61	[1.41; 1.83]	0.168

*Δ = change in outcome after program intervention (T1-T0); evolution of proportions is shown as the absolute difference

† OR = the odds ratio for obtaining vs. not obtaining the target before and after the intervention

‡ Significance level of $p < 0.05$ for outcome changes in CI vs. AQIP, determined by GEE model. The effects were adjusted for the clustering of patients within practices.

Table 3. Improvement of HbA1c, SBP and LDL-C and therapy intensification

Range of initial values	N	Mean Baseline Value ± SD	Mean change ± SD	p^{Π}	Therapy changes during intervention Proportion†‡§	RC*	p‖
HbA1c (%)					**Initiation of insulin†**		
< 7	1324	6.32 ± 0.4	0.0 ± 0.57	0.4027	1.5%	1	
7%-7.9	655	7.37 ± 0.28	-0.4 ± 0.80	<0.0001	6%	3.6	< 0.0001
≥ 8	464	9.17 ± 1.30	-1.6 ± 1.28	<0.0001	18%	10.9	< 0.0001
SBP (mm Hg)					**BP lowering drug change‡**		
≤ 130	1230	124 ± 7	0.4 ± 12	0.1396	19%	1	
131 – 140	599	138 ± 3	-4 ± 13	<0.0001	22%	1.2	0.1061
141 -160	509	152 ± 6	-12 ± 15	<0.0001	29%	1.5	< 0.0001
> 160	146	175 ± 13	-28 ± 19	<0.0001	34%	1.8	< 0.0001
LDL-C (mg / dl)					**Initiation of statins§**		
< 100	900	78 ± 16	1 ± 25	0.9670	21%	1	
100 – 114	404	107 ± 4	-9 ± 24	0.0006	23%	1.1	0.5182
115 -129	324	122 ± 4	-15 ± 28	<0.0001	25%	1.2	0.2209
≥ 130	532	153 ± 21	-49 ± 37	<0.0001	40%	1.9	< 0.0001

* RC = relative chance of therapy change compared to the patient group reaching the ADA-target

† for insulin: number of patients with insulin initiation divided by total patients without baseline insulin therapy

‡ for BP lowering drugs: number of patients with prescription of at least 1 new drug during the intervention divided by total patients

§ for statins: number of patients with statin initiation divided by total patients without baseline statin therapy

‖ significance level of $p < 0.05$, determined with logistic mixed models for the Relative Chance on changes in drug therapy, compared to the subgroup of patients at target.

ΠSignificance level of $p<0.05$, determined with linear mixed models for change in HbA1c, SBP and LDL-C of various subgroups out of control compared to the subgroup that is at baseline in control.

Figure 1. Enrolment of physicians and patients in the study

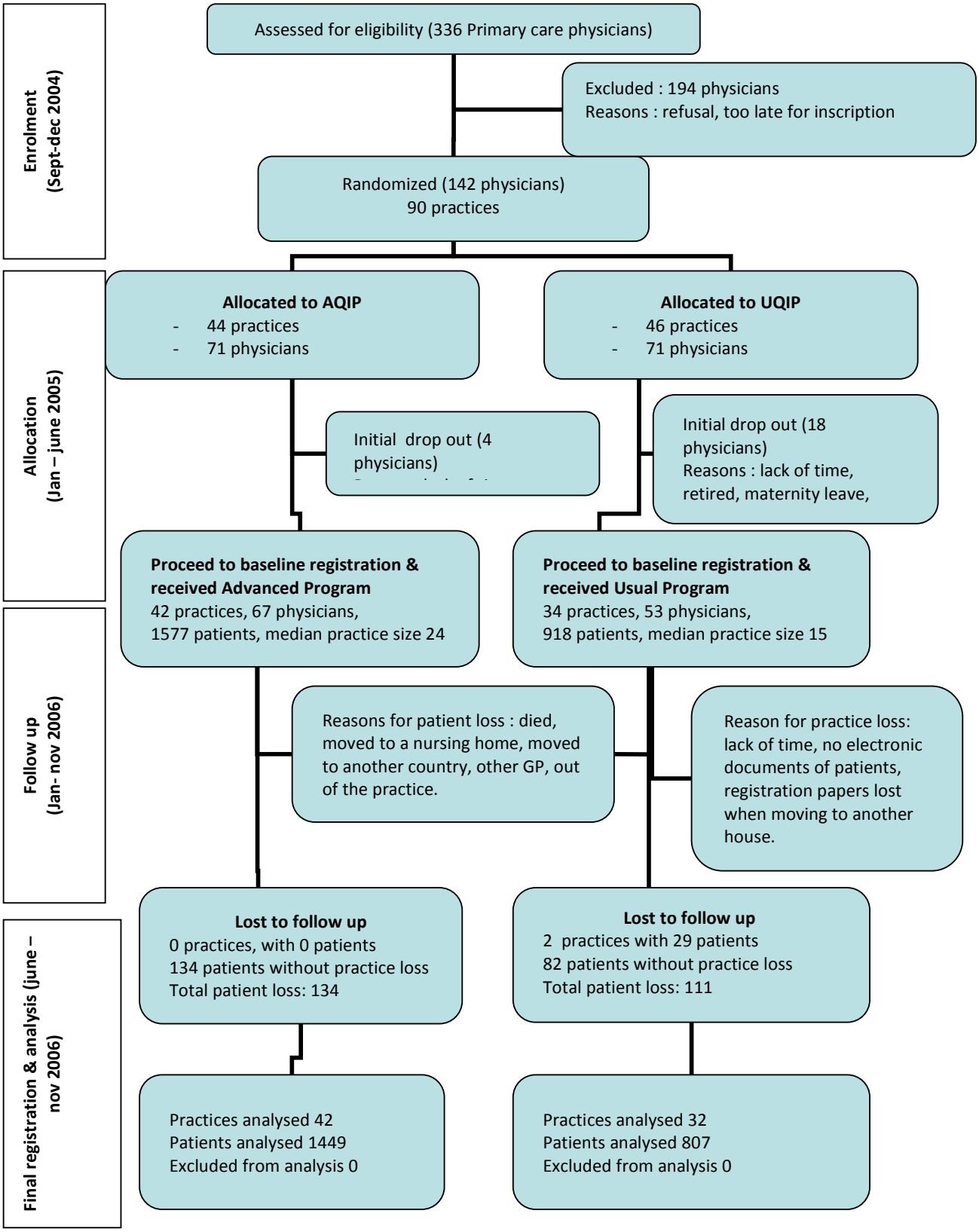
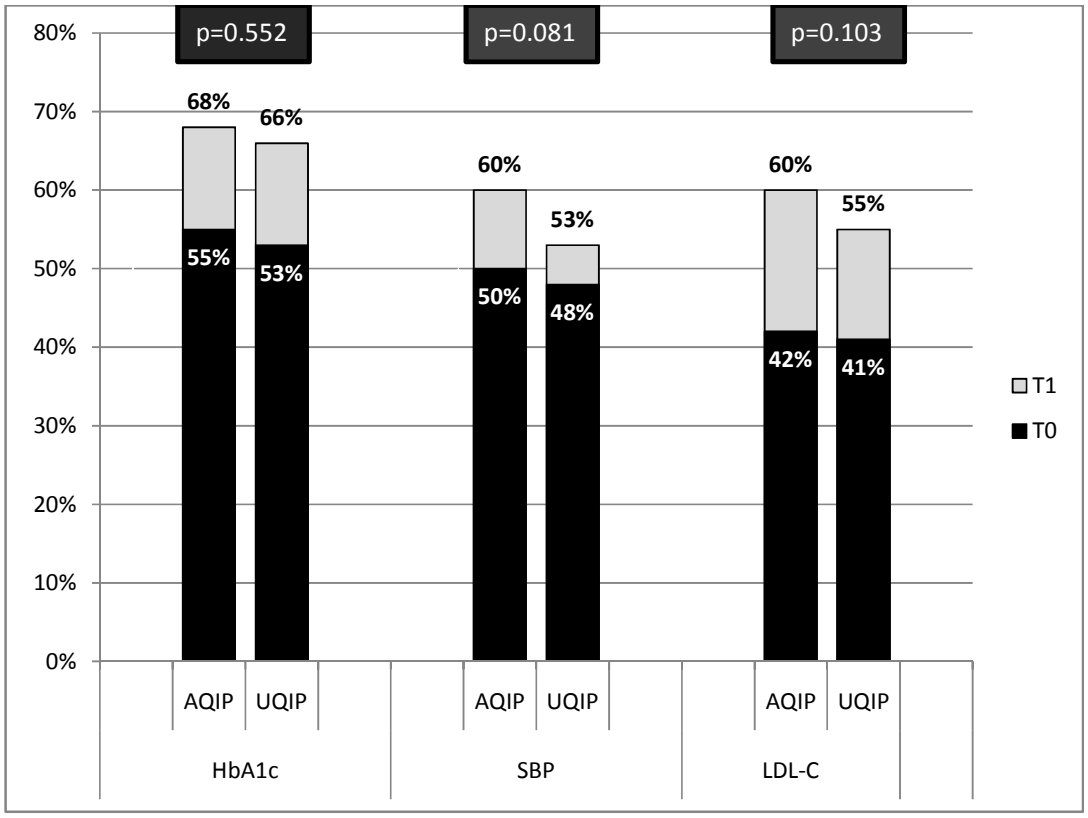


Figure 2. Proportion of patients on target at T0 and T1



Legend: Targets derived from the ADA guidelines: HbA1c < 7%; SBP ≤ 130 mm Hg; LDL-C < 100 mg/dl.

AQIP = Advanced Quality Improvement Program (67 GPs, 1577 patients); UQIP = Usual Quality Improvement Program (53 GPs, 918 patients) ; T0 = baseline ; T1 = post intervention

CI 95% AQIP T0 HbA1c [54-57] ; SBP [49-52] ; LDL-C [41-43] ; T1 HbA1c [67-69] ; SBP [59-61] ; LDL-C [59-62]

CI95% UQIP T0 HbA1c [52-56] ; SBP [46-49] ; LDL-C [39-43] ; T1 HbA1c [64-67] ; SBP [52-55] ; LDL-C [53-57]

p = significance level for the difference in change in AQIP vs. UQIP, determined by GEE. Effects were adjusted for the clustering of patients within practices.

Addendum. Specific strategies to implement the LDP Quality Improvement Program, divided according to the analysed barriers and the level of action.

Level	Barrier	Intervention
Program	Insufficient knowledge of the barriers and facilitators to quality improvement	- Initial barrier analyses (stakeholders/GPs) - Analysis of the social and local context
Guidelines	Too complex and not adapted to General Practice	- Clear, scientific and attractive treatment protocol - Involvement of opinion leaders in the outline of the protocol - Involvement of the target audience (GPs) in the outline of the protocol
GP-practice	Routine in follow-up	- Diabetes registries to picture the diabetes population - Clear protocol with follow-up schemes and reminders to follow the protocol - Reminders to change practice organization - Task arrangements and shared care protocol - Offer of multidisciplinary diabetes consultations in practice
	Lack of Time to accomplish EBM management	- Task redistribution (IDCT) - Logistic support - Appeal to make changes in practice organization
	Lack of a protocol-based, standardized follow-up of type diabetes patients	- Follow-up scheme - Reminders to register and thus to assure follow-up
	Lack of familiarity with shared care involvement	- Shared care protocol - Reminders to actively encourage referral to IDCT
	Insufficient 'reflexes' to share care with other disciplines ('colloque singulier')	- Shared care protocol - Reminders to share care
	Fear of government interference, control and sanctioning policy	- Professional implementation program led by a multidisciplinary team - Special attention to careful communication - Phasing of the program according to the motivational stage of the GPs - Use of GPs with moral authority (responsible of local professional organizations) - Revaluation of the GP role and positive motivation to participate - Reassurance on positive intentions (no control)
	Suboptimal organization: absence of logistic support (solo practices), absence of organized consults with an appointment system, absence of practice diabetes registries	- Appeals to reorganize diabetes care at practice level - Creation of diabetes registries - Logistic support at regional level
	Inadequate knowledge about treatment targets, global treatment beyond glycemic control, insulin onset, motivational communication techniques and possibilities for shared care	- CME on EBM, insulin, communication and shared care
	Lack of 'self knowledge' by lack of data feedback	- Benchmarking feedback
	Skepticism about the added value of unwell known innovations (health psychologist, internal medical doctor)	- Extra reminders to stress the use of these disciplines
	Clinical inertia in diabetes treatment (glycemic and blood pressure control)	- Emphasis on target driven treatment

Patient	Lack of disease insight ('a little touch of sugar ; no symptoms')	- Creation of IDCT - Group educational meetings - Structured written educational materials - Communication training for GPs - Patient centered feedback
	Fear of insulin therapy ('end stage of the disease' vs. no symptoms; injections ; weight gain, side effects)	- IDCT with internal doctor and educator - GP education on insulin - Coherence in messages
	Lack of motivation to change lifestyle	- Educator/dietary advisor for free - Communication training for GPs - Collaboration with community campaigns
	Problems with medical therapy compliance	- Communication training for GPs - Shared Care - Patient centered feedback
	Insufficient involvement in its own treatment	- Educator/dietary advisor for free - Communication training for GPs
	Objective age and morbidity related problems, difficulties to leave home	- Educators at patients home
Social context	Competition with specialist care ("who's in charge of Type 2 Diabetes treatment?')	- Clear task arrangements (integrated care principles) o On patient related aspects (e.g. referral) o On coaching and communication - Facilitation of communication between GPs and specialists
regional organization	Absence of high skilled diabetes educators in the primary care	- IDCT with trained educator
	Absence of a clear task description between GPs, specialists and paramedical disciplines (nurses, dietary advisors)	- Shared care protocol
	Absence of the definition of one central responsible for the management of Type 2 Diabetes	- Clear responsibilities for all involved disciplines - GP = central 'patient manager'
	Absence of specific diabetes teams supporting general practitioners	- Creation of IDCT
	Absence of regional diabetes registries and quality monitoring systems	- Creation of regional database register
	Absence of logistic support at regional level inducing the absence of organized communication between disciplines, absence of organized education programs, monitoring systems, quality evaluation.	- Necessary role of the central 'program manager' or 'promotor'
health care system	Inadequate payment of providers (fee for service)	- A fixed fee for each included patient
health care system	Important financial barriers for patient concerning auto test material and reimbursement of dietary advice and some insulin treatments	- Educator/dietary advisor for free - Test material for free if insulin therapy

Chapter 3: The 2002 – 2007 Evolution of the Quality of Care for People with Type 2 Diabetes Receiving Glucose Lowering Medication: a Registry Based Study.

Translated from the report for to the National Institute for Health and Disability Insurance (NIHDI, RIZIV): *"De evolutie in de kwaliteit van zorg voor Type 2 Diabetespatiënten in de regio Leuven tussen 2002 en 2007."* Geert Goderis, Carine Van Den Broeke, Liesbeth Borgermans, Jan Heyrman, Anna Ivanova, An Carbonez Geert Verbeke, December 2009.

Background

The use of insurance claims data to assess the evolution of disease related outcomes provides certain advantages in the evaluation of the quality of chronic diseases. It enables the possibility to evaluate a long period of follow-up since most data are stocked for at least five years. It is relatively cheap because it makes use of existing data and it assesses 'real life' situations without experimental interference. As such registry based studies have several advantages compared to experimental designs, like cross sectional or longitudinal studies of specific selected cohort of patients. Cohort studies with a selected study population need to be recruited and thus those trials always contain the risk to interfere with the spontaneous behaviour of professionals and patients. Moreover, they are always limited in the number of observed persons. However, claims data mostly only contain consumer data, i.e. data that refer to the use of certain medical services. Most of these data do contain neither disease diagnoses nor outcome data. As such, these data could only be used in the follow-up of certain process parameters, e.g. the frequency of HbA1c measurement. Yet, in the case of (Type 2) diabetes, two of the most important outcome parameters (HbA1c and LDL-C) are laboratory measurements stocked in laboratory databases. Moreover, we were particularly interested in the regional impact of a Quality Improvement Program that took place between 1/1/2005 and 30/11/2006. In this project, 120 out of 336 active General Practitioners (GPs) in the region of Leuven (Belgium) volunteered to include 2495 Type 2 patients for 18 months of follow-up. The program was associated with a siginificant improvement over time of HbA1c (from 7.1%±1.3% to 6.7%±1.0%), Total Cholesterol, LDL-C (from 108mg/dl ± 34 mg/dl to) and HDL-C.

The use of insurance claims data combined with laboratory data allows for interpreting the obtained results within a larger timeframe and within a regional context. It could also enable a comparison between the changes in the aforementioned parameters of patients clustered around GPs who were involved in the project versus the change in those clustered around GPs who were not involved in the project.

The primary objective of this study was to evaluate the 5-year evolution of outcome and process parameters in the care for persons living in the region of Leuven before the start of the project (1/1/2005) and who have been treated by

glucose lowering medication since at least 2002. The primary outcome measure was the change in HbA1c and cholesterol values (Total cholesterol and LDL-cholesterol). The secondary outcome measure was the change in several process parameters such as the annual frequency of HbA1c measurement, total cholesterol measurement, fundoscopy (eye examination), microalbuminuria measurement and flu vaccination and the change in the proportion of patients on insulin and statin therapy. Additionally, we wanted to evaluate whether the change in those parameters in patients clustered around the 'participating GPs' was significantly different from the change in parameters of patients clustered around GPs who were not indicated as participating GPs.

Methods

Selection of the research population

In Belgium each act or service from a health care professional towards a patient receives a different code. A consult with a GP receives a specific code, a consult with a specialist receives another code, the laboratory test to determine the HbA1c level again another code, and the delivery of a specific drugs another one, and so on. Many hundreds or even thousands of codes exist and all these codes serve to reimburse the patients when they have paid for that act or to directly pay the health professional. The payment or reimbursement institute is the National Institute for Health and Disability Insurance, but the payment itself is done through specific health assurance companies, called 'mutualiteiten'. These companies also collect and stock all those data (codes) and associated costs. Each person living in Belgium has a unique code, called the "INSZ"-code. The health care companies have the right to stock personal data with this code as identification key. As such, those data can serve to evaluate the health care consumption and related costs. However, the data are collected and stocked by 7 different companies. One agency, the 'Inter Mutualistic Agency' (IMA) serves as an interface between those companies to merge those different databases. In our case, the IMA served as an interface between our research group and the health insurance companies. The project has received written approval by the national privacy committee in May 2008. This approval elaborated a legal framework that enabled the analysis of the combined insurance claims data and laboratory data with respect to the privacy rules and without the

need of individual informed patient consent. All data had to be double coded implying the intervention of a Trusted Third Party (IBM).

We were interested in consumer data concerning Type 2 Diabetes patients in the region surrounding the University Hospital of Leuven (and associated researchers were interested in the same data of patients living in the regions Aalst and St. Niklaas). Since the databases did not contain data about diagnoses, the selection of the diabetic population needed to be done by a two step selection procedure. First we selected a 'too large sample' using indirect "*large selection criteria*" that possibly could indicate the presence of Type 2 Diabetes (see table 1). Patients in this database could be labelled as "*potential Type 2 Diabetes patients*". We asked the IMA to order data between 1/1/2002 and 01/01/2007 of all patients of the region Leuven who fulfilled these criteria. These data were delivered by the IMA in four different databases and are called "consumer data", "population data", "medication data" and "insurance costs". More specifically, we asked the IMA to collect detailed data about the following parameters: year of birth, gender, year and month of death, contacts with GPs and other professionals (+ date of contacts), medication (glucose lowering, blood pressure lowering and lipid lowering medication, anti-platelet therapy and flu vaccination), hospital admissions, laboratory and technical acts (e.g. HbA1c measurement, eye examination).We also ordered to deliver the costs of each act. In the meanwhile, we asked all laboratories in the region to deliver data on patients with HbA1c tests during 2002 and 2006. Laboratories were asked to select patients (with INSZ codes) meeting following criteria: all patients older than 35 years at 1/1/2002, with at least 1 HbA1c-measurement between 1/1/2002 and 01/01/2007 and living in the indicated regions (Leuven, Aalst, St.Niklaas). We asked laboratory to deliver following data (+ date of measurement): glycemia, Hba1c, total cholesterol, HDL-cholesterol, LDL-cholesterol, Triglycerides, serum creatinine, Microalbuminuria. There were 14 involved laboratories with 7 of them delivering data for the region of Leuven.

Besides the data issue from the IMA and the laboratories, we were allowed to bring in 'local data' from the Leuven Diabetes Project. We brought several patients in who were coded as 'participating patients'.

All these data issue from three different sources were linked to one "*merged database*" through a process of double coding. In order to respect the privacy rules,

we had to use a complex methodology with coding of all data issue from the health insurance companies, the laboratories and the local database. Each patient in the databases of the health insurance companies was presented by a D-code, by a B-code in the local database and by a C-code in the laboratory databases. In each database, the codes were linked with the INSZ number in so-called concordance tables. The health insurance companies sent all their data to the IMA who merged all databases in one "IMA database". The IMA data, the local data and the laboratory data were sent to the data manager. The concordance tables were sent to IBM who served as 'Trusted Third Party'. IBM changed the D-code into an E-code and ensured the concordance with the B-code and the C-code. Then IBM sent the unique concordance table containing the E-code linked to the B-code and C-code to the data manager who could now link the databases and merge the data by patients. As such, the "merged database" contained an enormous amount of consumer and laboratory data of 'potential Type 2 Diabetes patients' living in the region of Leuven, Aalst and St. Niklaas. In the region of Leuven, several patients were 'tagged' and thus could be identified as patients who really participated to the original LDP Quality Improvement Program. Unfortunately, it was not possible to bring in all participating patients because not all INSZ-codes could be collected. The flow chart that shows the data collection, coding and merging of the data is shown in figure 1.

In a next step, we 'tagged' those GPs who participated to the LDP project. In Belgium, general practices do not have patient registries as patients have free access to medical services. However, each patient can choose a 'preferred GP' (code 102771) on a voluntary basis. Most of the diabetes patients do have a preferred GP because the NIHDI wants to stimulate patients to choose one preferred GP. It is also compulsory for diabetes patients to choose a preferred GP in order to have certain limited advantages as a certain access to reimbursement of dietary advice. We used this code to indicate the participating GPs as those GPs characterized by clusters of tagged participating patients in the merged database. In a next step, we used "*refined inclusion criteria*" to select a subset of "*highly probable Type 2 Diabetes patients*" out of the merged database. This was a necessary step because the merged database also contained type 1 diabetes patients and non diabetic patients taking metformin. Again, we had to use indirect criteria without possibility to control whether we really excluded non Type 2 Diabetes patients

without excluding Type 2 Diabetes patient. All selected patients had to meet the following inclusion criterion: to have received at least once a glucose lowering medication between 2002 and 2006. Were excluded from selection, those patients (1) who were coded as Type 1 Diabetes patients (this is a code in the diabetes convention 786 that only exists since 2006), (2) patients who were coded as adhering to a diabetes clinic and receiving 3 daily insulin injections or more, (3) patients who only take metformin and who did not have 2 succeeding HbA1c measurements within a timeframe of 1 year. We excluded patients with complex insulin schemes (≥ 3 daily insulin injections) because we assumed that most type 1 diabetes patients receive those more complex. We excluded patients with only metformin and without two consecutive HbA1c measurements within 1 year in an attempt to exclude non diabetic patients taking metformin.

The final step was to select the definitive research sample. We wanted to select a 'stable' cohort of diabetes patients known since 2002. Therefore, to be included in the research sample, patients had to take glucose lowering drugs since 2002. No additional influx of new patients after 2002 was allowed. All patients also had to live in the region of Leuven before the start of the LDP project (1/1/2005). Furthermore patients who were clustered by a "preferred GP code" to a participating GP were indicated as 'participating patients'. The 'PICO' design is shown in table 2. The scheme of the trial from research question to sample selection is shown in figure 2.

Statistical analysis

The change in patient outcomes between 01/01/2002 and 01/01/2007 was analyzed using a mixed model with broken line technique and with 01/01/05, the day LDP started as cut-off date. This technique allows for different evolutions before the start of the intervention (01/01/2002-01/01/2005) and after the start of the intervention (01/01/20005-01/01/2007). HbA1c, Total Cholesterol and LDL-Cholesterol were set as response variables but were log transformed because of the skewness. The time variable was split up in two variables ('Time1', before the start of the intervention and 'Time2' after the start of the intervention). Time, the group variable ('LDP' vs. 'non LDP') and the interaction between the group variable and the time variables were set as fixed effects. The 'LDP' group included those patients clustered with a preferred GP code to a GP who participated to the project. The 'Non LDP' group included patients clustered with a preferred GP code to another GP. Since all outcomes were

clustered within the patients, the patient was set as random effect. The change in parameters between the LDP and non-LDP group were compared before the start of the intervention and again after the start of the intervention. Additionally, within both groups, the real change after the start of the intervention was compared with the predicted evolution, i.e. the evolution of the parameter when the evolution before the start of the intervention was extrapolated until 31/12/2006. Between group-analyses of discrete variables were performed using Mantel-Haenzel Chi-Square tests.

Results

As shown in table 3, the merged database contained data on 41547 "potential Type 2 Diabetes patients" from whom 26 255 were living in the region of Leuven. After applying the refined selection criteria, we obtained a database with 8388 "probable Type 2 Diabetes patients receiving glucose lowering medication." 4595 patients already lived in the region of Leuven before the start of the project and have received glucose lowering medication at least since 2002. 1569 of them were clustered around GPs who participated to the LDP project and were named 'LDP-group'; 3026 patients were clustered around other GPs and were named 'non-LDP-group'. Mean age in both groups was 71±11 years with 53% female patients, again in both groups. The results of the outcome parameters as presented in table 4 are not derived from descriptive statistics but are provided by the mixed model. The HbA1c-change was similar in both groups. Before the start of the LDP-intervention, we observed an increase from 6.9% to 7.1% at 1/1/2005 followed by a decrease after the intervention with a value of 6.8% at 1/1/2007. This decrease was significantly different from the predicted change in both groups. Interestingly, both total cholesterol and LDL-C values decreased between 2002 and 2005 both in the LDP (-20 mg/dl) and non-LDP group (-19 mg/dl). Total cholesterol values decreased from 208 mg/dl at 1/1/02 in the LDP group to 188 mg/dl at 1/1/2005 (-20 mg/dl) and from 205 mg/dl at 1/1/02 to 186 mg/dl at 1/1/05 in the non LDP group (-19 mg/dl). We observed a similar decrease in LDL-Cholesterol values with a decrease of 21 mg/dl in the LDP group and 20 mg/dl in the non LDP group. After the start of the intervention, lipid values decreased even more rapidly in both groups. The real change in respectively the Total Cholesterol and LDL-C was significantly different from the predicted evolution both in the LDP group (-22 mg/dl and – 20 mg/dl vs. -12 mg/dl and -13 mg/dl) and in the non-LDP group (-18 mg/dl and -16mg/dl vs. -12 m/dl and -11 mg/dl). The change in lipid values

before the start of the intervention was not significantly different between both groups. However, after the start of the intervention, both Total Cholesterol and LDL-C decreased significantly more in the LDP group vs. non LDP-group (Total cholesterol: - 22 mg/dl vs. – 18 mg/dl, p=0.0034; LDL-C – 20 mg/dl vs. -16 mg/dl, p=0.0314). As shown in figure 3, the proportion of patients reaching a HbA1c target of 7% decreased both in the LDP and non LDP group from 2002 (57% vs. 55%) to 2004 (47% vs. 49%) and afterwards increased in 2005 (50% vs. 50%) and 2006 (54% vs. 54%). The proportion of patients reaching a LDL-C target of 100 mg/dl increased in both groups from 25% (LDP) and 28% (non LDP) in 2002 to 57% (LDP) and 58% (non LDP). The most important increase in both groups was observed in the two years after 2004 (+ 25% in the LDP group and + 24% in the non LDP group). Analysis of process measures like the annual eye examination, annual micro-albuminuria measurement, HbA1c and Cholesterol measurement showed several points of interest (figure 4 and 5). First, the proportion of patients with an annual micro-albuminuria screening and at least 1 Hba1c measurement has been significantly higher in the LDP group vs. non LDP group since 2002. Second, the annual follow-up of HbA1c and cholesterol has been satisfactory (> 75%) in both groups since 2002. However, less than half of the patients receive an annual eye examination and less than 25% of the patients received an annual micro-albuminuria screening. Third, all process parameters improved in the LDP group after 2004 (especially in 2005), but not or almost not in the non LDP group. As such, the proportion of patients with an annual eye examination became significantly higher in the LDP group in 2005 (p=0.0009) and the difference in the proportion of patients with at least 1 annual cholesterol measurement became significant in 2005 (LDP 89% vs. Non LDP 79%, p<0.0001) and 2006 (LDP 88% vs. non LDP 79%, p<0.0001). The difference in the proportion of patients with at least one annual HbA1c measurement was also maximal in 2005 (LDP 91% vs. non LDP 80%, p<0.0001). Finally, significantly more patients of the LDP group received statin therapy in 2005 (48% vs. 44%, p=0.0068) and 2006 (53% vs. 49%, p=0.0126) and insulin therapy in 2006 (29% vs. 26%, p=0.0134).

Discussion

The present study describes the five year (2002-2007) evolution of HbA1c and cholesterol values of patients who have received glucose lowering medication at least since 2002 and who already lived in the region of Leuven before 1/1/2005. The primary outcome measure was the change in HbA1c and LDL-cholesterol. The secondary outcome measure was the change in process parameters such as the annual frequency of HbA1c measurement, total cholesterol measurement, eye examination, microalbuminuria measurement and the change in the proportion of patients on insulin and statin therapy. The region of Leuven was the setting of a Quality Improvement Program (LDP) between 1/1/2005 and 30/11/2006. We have evaluated whether the change in HbA1c and cholesterol values in patients clustered around participating GPs in the LDP project was significantly different from the change in HbA1c and cholesterol values in patients clustered around GPs who were not indicated as participating GPs. We merged consumer data originated out of databases from health insurance companies with data issued from laboratory registries. This methodology was prone to several problems and possible biases. The process of data collection, coding and merging of databases, defining selection criteria and selecting the research sample nearly took one year. The problems, limitations and potential biases that we have encountered in this project are too numerous to mention all of them in this chapter. They are described in detail in the available NIHDI reports. Globally we can state that the results of this study have to be interpreted with a lot of care. In our opinion, the results cannot be generalized to the "diabetic population" in Belgium. Interpretation of the results must stick to those patients who are selected in the research sample. The main problem was that the diagnosis (of Type 2 Diabetes) was not present in the database. We had to select a subgroup of probable Type 2 Diabetes patients, those on glucose lowering drugs with some additional criteria to exclude probable Type 1 Diabetes patients and patients taking metformin without suffering from diabetes. We assumed that most type 1 diabetes patients receive more complex insulin schemes (≥ 3 daily insulin injections) and thus, by excluding the group of intensively treated patients, we think we have excluded the majority of type 1 diabetes patients. We are aware that we also excluded a number of intensively treated Type 2 Diabetes patients. We judged this loss acceptable because those patients are nearly exclusively treated in the diabetes

clinics and are supposed to have less benefit from the Quality Improvement Program (see chapter 1). We also lost all Type 2 Diabetes patients who did not take any glucose lowering medication, an estimated loss of 13% of all Type 2 Diabetes patients. On the other hand, we cannot exclude that non diabetic patients taking metformin are really excluded from the research sample. Further on, we had to identify GPs who participated in the LDP in an indirect way by a process of clustering 'tagged LDP-patients' patients. We succeeded this procedure but because of privacy matters, we could not control if the 'participating GPs' were really those who participated in the LDP. In a further stage, we had to find a method to cluster patients around the 'tagged' LDP GPs'. Therefore, we used the code of 'preferred GP'. However, as a consequence of this procedure, we could only select a group of patients who were clustered around GPs supposed to have participated in the original LDP project. We could not verify whether all these patients really were involved in the original LDP project. Moreover, not all patients who participated in the original project have a preferred GP and those patients were lost in this study. Another limitation of the study is due to the nature of the laboratory data. Data were collected from 9 different laboratories and some laboratories changed from machine or technique during this period. Analysis may have been biased because new methods are likely to measure somewhat lower. It is however impossible to quantify this bias.

Because of all these uncertainties and possible biases, we decided that the first objective of this study should be the description of the 5-year evolution of the care for persons treated by glucose lowering medication in a region that was the setting of a Quality Improvement Program (LDP) for the last two years of this period. And thus, we had to create a 'stable cohort' of Type 2 Diabetes patients. Therefore we selected patients who have received glucose lowering medication since at least 2002 and who already lived in the region before the start of the project. As a consequence, all patients who were diagnosed with Type 2 Diabetes patients after 2002 and who participated to the LDP were also lost in the present study. As such, when interpreting the comparison between 'participating' patients and 'reference patients', one must know that in reality, it is a comparison between patients receiving glucose lowering medication at least since 2002 who are clustered by the 'preferred GP code' around GPs who probably participated in the LDP project between

1/1/2005 and 30/11/2006 versus the same type of patients, but who were clustered around another GP according to this 'preferred GP code'. A last important limitation is the fact that DCCT standardization of the laboratory procedures for HbA1c determination was only available since 2003. The problem of different involved laboratories is not very important for the region of Leuven since the huge majority of data are collected by three laboratories using the same technique and standardization. However, the data concerning the year 2002 may be from a different nature of the data in the following years, although this assumption is refuted by the results themselves. We did not observe a 'rupture' in the HbA1c evolution between 2002 and 2003. This might be the consequence of the fact that nearly all results (97%) are derived from three laboratories that used DCCT aligned techniques already before 2003.

The results however remain interesting. The value of HbA1c increased and the proportion of patients reaching the target (< 7%) decreased before the start of the project until 2004. This evolution was unsurprisingly because Type 2 Diabetes is a disease that naturally deteriorates. However, since 2005, the proportion of patients reaching the targets has increased again and HbA1c values have decreased. This evolution was not only observed in the patients clustered around participating GPs, but also in patients of GPs who did not participate. These results are contradictory to the natural evolution of the disease and thus indicate that a change has occurred in the glucose treatment of diabetic patients in the region of Leuven. This change might have been induced by the LDP and the project may have 'contaminated' non participating practices and patients. However, other factors like published recommendations and other quality improvement initiatives that increased the attention to diabetes treatment may have played a role. The evolution of cholesterol values is even more interesting. We observed an important decrease in both Total and LDL-C values before the start of the project in both groups. These results indicate that the recommendation to treat cholesterol in patients with diabetes was already implemented before the start of the project. However, our results also indicate that the project boosted this implementation because the observed decrease in total cholesterol and LDL-C after 2005 is significantly different than the expected decrease. Moreover, we observed the highest increase in the proportion of patients reaching the LDL-Cholesterol in the years 2005 and 2006, especially in patients

clustered around participating GPs. The analysis of the process parameters furthers allows gaining more insight in the diabetes care and the Quality Improvement Program. First, the results suggest that the selected cohort of participating GPs is different from non participating GPs since some crucial process parameters (HbA1c measurement and micro-albuminuria measurement) were significantly different far before the start of the project. Secondly, follow-up of the more 'classical' process parameters like Hba1c and cholesterol measurement has been satisfactory in the large majority of all included patients. However, there is a lot of room for improvement in the screening tests for eye and kidney complications. Thirdly, we observed a consistent improvement in all process parameters in the year 2005 in the LDP group, followed by a small decrease in the year 2006. These results show that the cohort that was selected as "participating GPs" indeed corresponds with the original cohort of GPs who participated to the quality improvement project. Moreover, they indicate that the Quality Improvement Program has favourably influenced quality of the process of diabetes care of the participating GPs. Finally, significant differences were observed between the LDP and on LDP group in the evolution of the proportion of patients receiving statin and insulin therapy. These differences were too small or occurred too late to have an impact on patients' outcome values. However, these results suggest that continued observation could have shown a difference at the outcome level between the LDP and non LDP group.

In conclusion, studies based on patient registries can be useful to evaluate the long-time evolution of diabetes related outcomes. They allow for evaluating results of a high number of patients all over the country without the necessity to set up specific trials. The results of these study designs should be interpreted with the necessary caution because of several sources of bias. The main problems were caused by the privacy legislation and the absence of coed diagnosis in the insurance claims databases. Taking into account these limitations, it is possible to state that a change in glucose treatment in patients with diabetes occurred in the region of Leuven in the period that the Leuven Diabetes Project started up. It is also possible to state that cholesterol treatment was implemented in the region far before the start of the project, but the project may have boosted this implementation. Finally, there is enough consistency in the evolution of the different process parameters to state that

the quality improvement project has favourably influenced the quality of process of diabetes care of the GPs who participated to this project.

Table 1: Different selection to compose the research sample.

A. ***1. "Large selection criteria"*** to select potential Type 2 Diabetes patients. Patients were selected out of the databases of health insurance companies.	
A patient is selected as potential Type 2 Diabetes patient if he/she meets criteria 1 AND 2 AND meets at least one of the criteria 3, 4, 5 OR 6	
1. Patients living in the region of Leuven (and Aalst and St. Niklaas, but these regions do not consider the LDP project) between 1/1/2004 en 31/12/2006	
2. Patients born in 1966 or before that year (minimum age 40 years at the start of the LDP)	
3. Patients with at least 1 Hba1c measurement (code 540750) between 1/1/2002 and 31/12/2006	
4. Patients who have received a 'diabetes pass'. The diabetes pass was introduced at March 1° 2003, but a code (102852) only exists since January 31° 2006	
5. Patients adhering to the convention 786. For those patients, one of the following codes has at least one time been introduced in a health Insurance company database between 1/1/2002 and 31/12/2006: 773231, 773253, 773275, 771573	
6. Patients who bought at least one time diabetes specific medication between 1/1/2002 and 31/12/2006: oral anti-diabetic medication (ATC code A10B) and/or insulin (ATC code A10A)	
A. ***2. Laboratory selection criteria***.	
1. patients must be older than 35 years at 1/1/2002,	
2. with at least 1 HbA1c result between 1/1/2002 and 31/12/2006	
3. living in the indicated regions (Leuven for LDP)	
B. **"*refined inclusion criteria*"** to select "highly probable Type 2 Diabetes patients"	
1. Inclusion criteria:	i. all patients are included who have received at least once a glucose lowering medication between 2002-2006. ii. and with presence in the database of the '*preferred GP code'* (at least one since 1/1/05)
2. Exclusion criteria: (and… and)	i. Patients who were coded as Type 1 Diabetes patients (this is a code in the diabetes convention 786 that only exists since 2006), ii. Patients who were coded as receiving 3 daily insulin injections or more iii. patients who only take metformin and who have not had 2 succeeding HbA1c measurements within a timeframe of 1 year
C. research sample criteria	
1. All patients who have received glucose lowering drugs since 2002. (No additional influx of new patients after 2002 was allowed.)	
2. And who already lived in the region of Leuven before the start of the LDP project (1/1/2005)	
D. Selection of the Intervention Population (participating patients)	
All patients who had a 'preferred GP code' with a participating GP.	

Table 2. PICO design of the registry based "Leuven Diabetes Project" research project.

P	All patients living in the region before the start of the project (1/1/2005), older than 40 years, taking glucose lowering medication since 2002 with as exception those patients known as type 1 diabetes patients, with 3 or more daily insulin injections or patients only taking metformin without 2 succeeding HbA1c measurements in a timeframe of 1 year
I	Patients clustered with a 'preferred GP code' around GPs who participated to the Leuven Diabetes Project
C	Patients clustered with a 'preferred GP code' around GPs who did not participate to the Leuven Diabetes Project
O	• The change in HbA1c, Total Cholesterol, LDL-cholesterol between 2002 and 2007. • The proportion of patients reaching predefined targets of HbA1c (7%) and LDL-cholesterol (100 mg/dl) • The change in the proportion of patients with annual HbA1c, Total Cholesterol, micro-albuminuria measurements and annual fundoscopy. • The change in the proportion of patients with insulin therapy and statin therapy

Table 3. Results of the data collection, merging and applying the different selection criteria.

Data delivered from different sources and with different contents			
Database	Contents (timeframe 2002 – 2006)	Number of records	Number of identifiable patients according to the unique E-code
IMA - "NCL" - database"	Consumer data: data concerning the use of medical and technical services	8 440 264	41 747
IMA - "GM" - database	Medication data coded by international codification (CNK codes)	2 585 822	36 372
IMA- "POP" - database	Population data (age, gender…)	38 709	41 767
IMA- ZIV-costs	Total Insurance costs per year	200 083	41 767
Laboratory	Outcomes 2002-2006	455 879	46 653
Merging the databases into 1 database			
Merged database	All data merged by patients		41547
Refining the selection criteria			

Patients who Live in the region of Leuven	26 255 (from total 41547)
And who have received at least once a glucose lowering medication between 2002 and 2006.	12 545
And with and with presence in the database of the '*preferred GP code' (at least one since 1/1/2005)*	9232
Number of patients after exclusion of type 1 and intensively treated Type 2 Diabetes patients, i.e. patients adhering by convention to a diabetes clinic and coded as receiving 3 or more daily insulin injections.	8474
Number of patients after exclusion of patients who take only metformine and who have not been measured HbA1c twice within a timeframe of 365 days.	8388
Patients who took anti-diabetic medication in 2002	4700
Patients who already lived in the region of Leuven before the start of the LDP project (1/1/2005)	4595
'Intervention' and 'control' population	
'Intervention' population: patients with a preferred GP code with a GP who participated to the LDP project	1569
'Control' population: patients with a preferred GP code with a GP who did not participate to the LDP project	3026

Table 4: Change in HbA1c, Total Cholesterol, LDL-Cholesterol and HDL-cholesterol between 2002 and 2006.

	Values at 1/1/2002	Values at 1/1/2005	Δ1	P*	Values at 1/1/2007	Δ2	P$^{\Psi}$	Predicted values at 1/1/2007	P°
HbA1c (%)									
LDP	6.9	7.1	+0.2	NS	6.8	-0.3	NS	7.2	p<0.0001
Non-LDP	6.9	7.1	+0.2		6.8	-0.3		7.2	p<0.0001
Total Cholesterol (mg/dl)									
LDP	208	188	-20	NS	166	-22	p=0.0034	176	p<0.0001
Non-LDP	205	186	-19		168	-18		174	p<0.0001
LDL-Cholesterol (mg/dl)									
LDP	125	104	-21	NS	84	-20	p=0.0314	91	p<0.0001
Non-LDP	121	101	-20		85	-16		90	p<0.0001

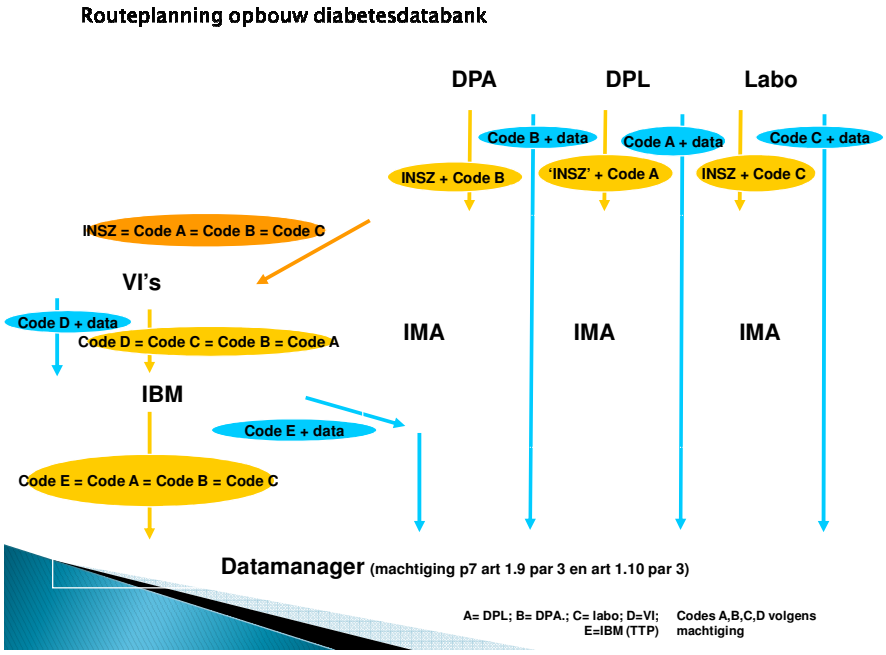
Δ1= change in values between 1/1/2002 and 1/1/2005; Δ2 = change in values between 1/1/2005 and 1/1/2007.

P*: testing whether the change in the parameter is significantly different in the LDP Group vs. Non LDP Group before the start of the intervention (1/1/2002 – 31/12/2004)

P$^{\Psi}$: testing whether the change in the parameter is significantly different in the "LDP Group" vs. "non LDP Group" after the start of the intervention (1/1/2005-31/12/2006)

P°: testing whether the 'real within group' change (1/1/2005-01/01/2007) of the parameter is significantly different from the predicted change (= extrapolation of the change between 1/1/2002 – 31/12/2004 until 31/12/2006)

Figure 1: flow chart in the construction of the “merged database”.



Legend of figure 2:

Preferred GP code = 102771 = the code that indicates that this patient is linked to a preferred GP.

Tagged patients = patients who surely participated to the LDP project and were made recognizable in the merged database as having participated (though anonymous)

Participating GPs = GPs characterized by cluster of tagged patients who have a ‘preferred GP code with the concerned GP’. As such, there is a lot of chance that those GPs really participated to the LDP project and thus they were probably involved in a quality improvement project.

Participating patients = patients clustered around a ‘participating GP’ according to the ‘preferred GP code’

Figure 2: Methodologic scheme of the Leuven Diabetes Project -

Analysis based on combined Insurance Claims Data & Laboratory Data

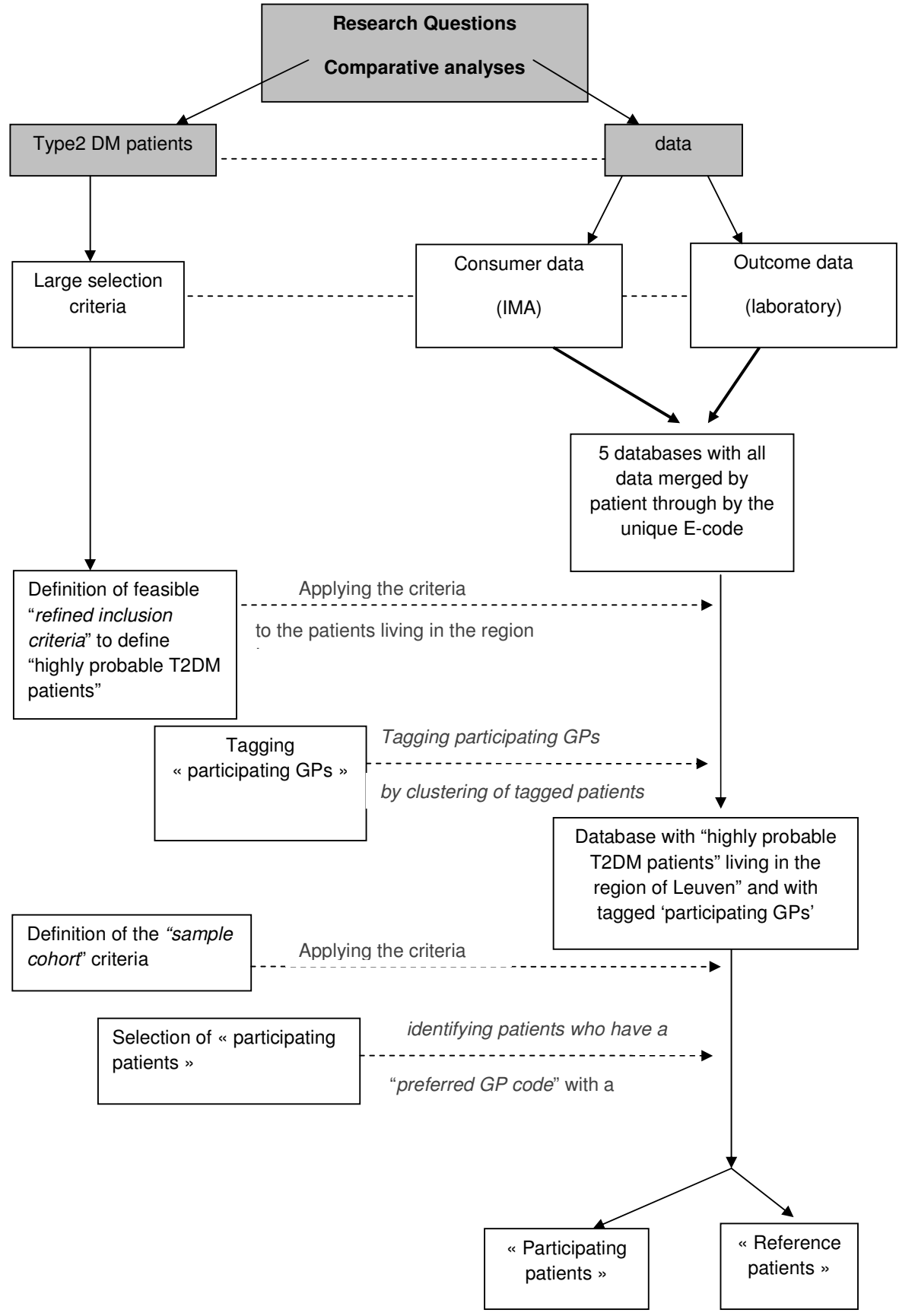
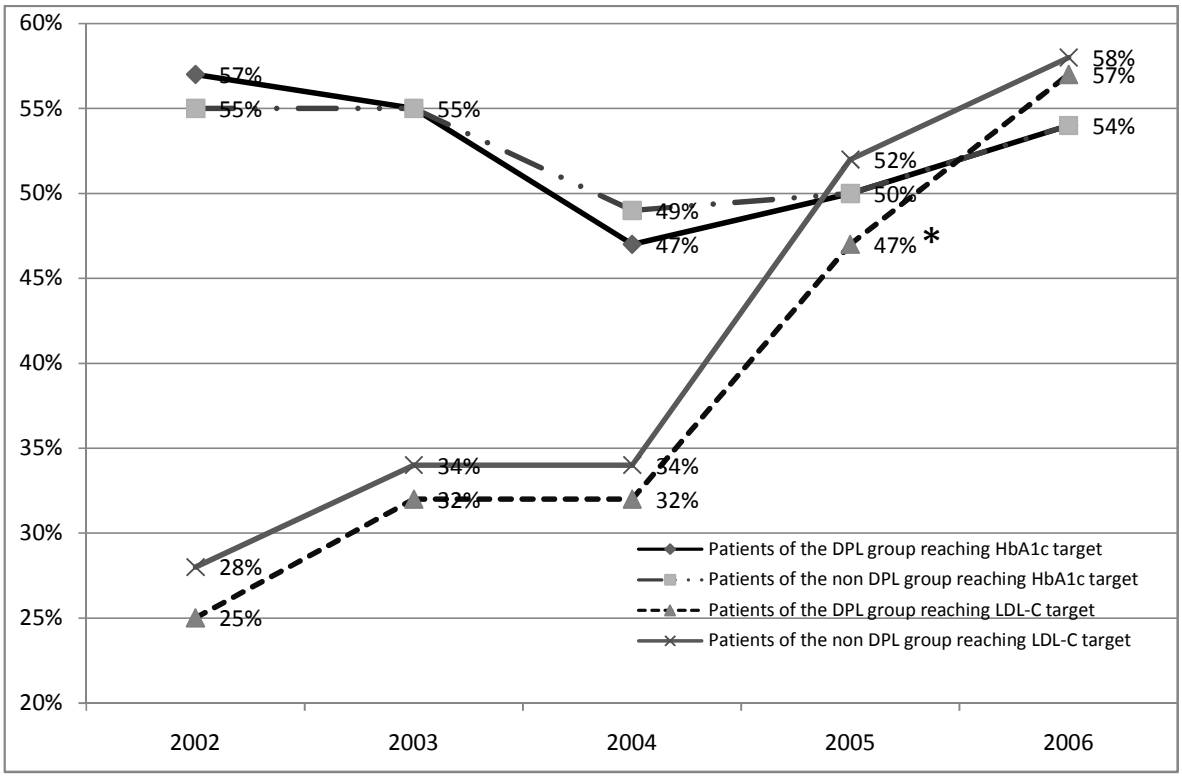
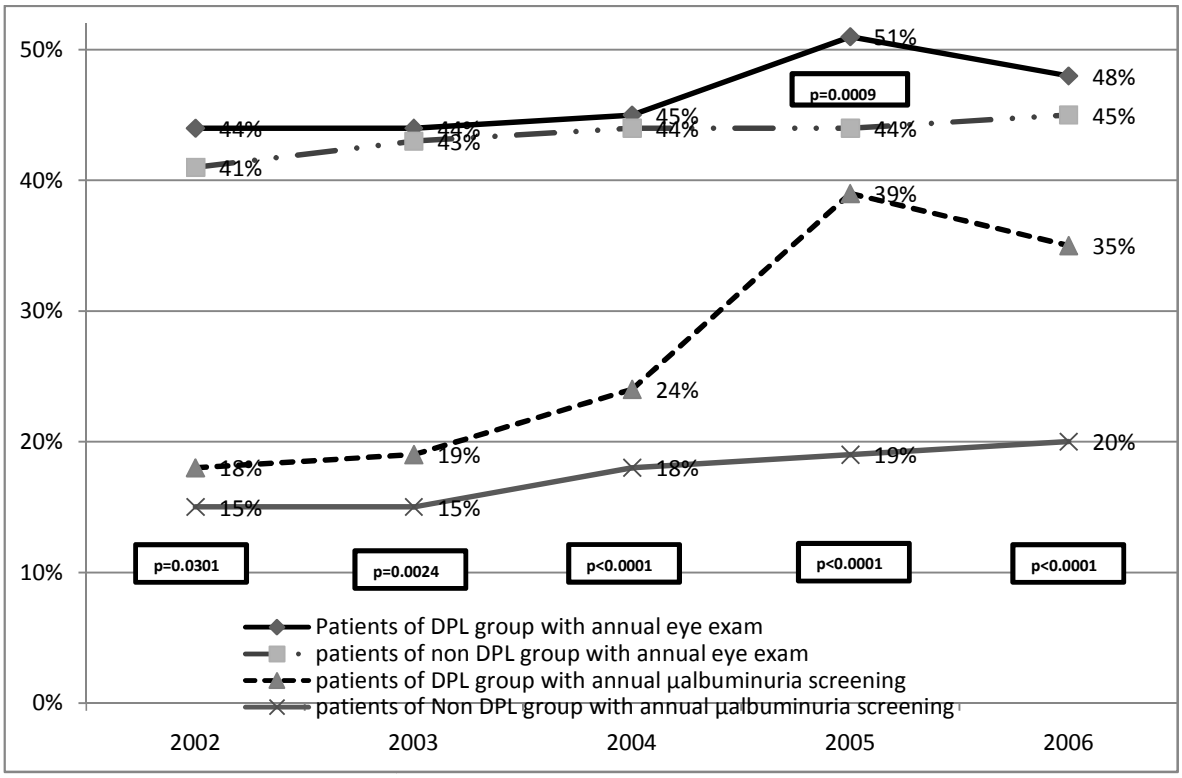


Figure 3. Evolution in the proportion of patients reaching predefined targets for HbA1c (7%) and LDL-Cholesterol (100 mg/dl)



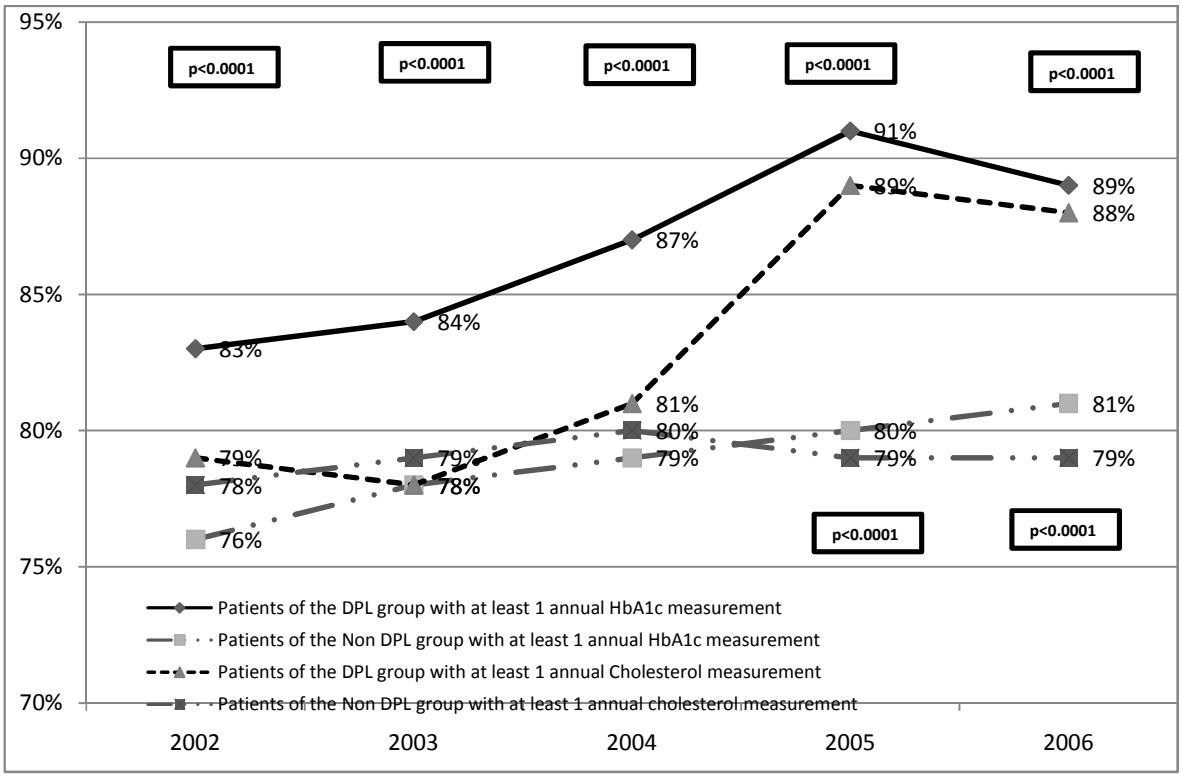
* The difference in the proportion of patients reaching the LDL-C target was significant in 2005 (Non LDP 52% vs. LDP 47%, p=0.0122) and faded away again in 2006.

Fig. 4: Evolution in the proportion of patients with at least 1 annual eye examination and at least one annual measurement of micro-albuminuria.



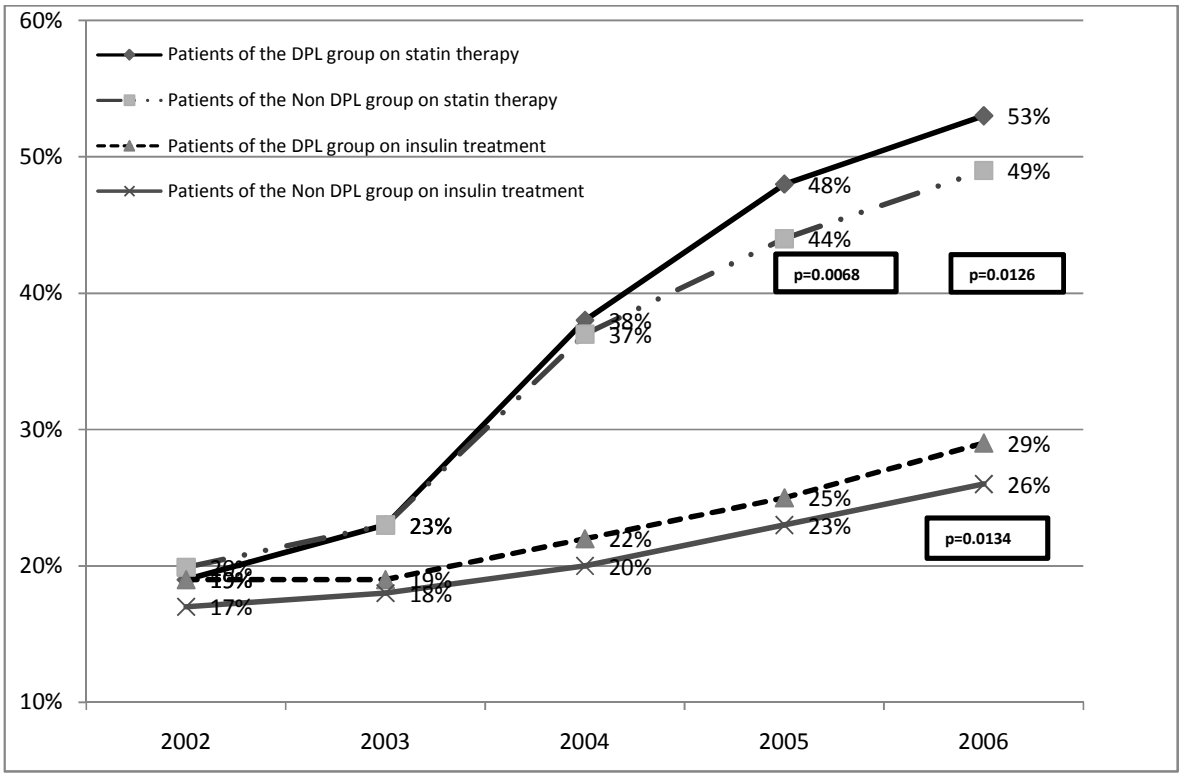
The proportion of patients with an annual eye examination was significantly higher in the LDP group in 2005, while the proportion of patients with at least one micro-albuminuria measurement was significantly higher in the LDP group in all years. However, also for micro-albuminuria testing, the difference between the LDP and non LDP group was maximal in 2005.

Fig. 5. Evolution in the proportion of patients with at least one annual HbA1c measurement and with at least one annual cholesterol measurement.



The proportion of patients with at least one annual Hba1c measurement was significantly higher in the LDP group in all years, but the difference between the LDP and non LDP group was maximal in 2005 (LDP 91% vs. Non LDP 80%). The difference in the proportion of patients with at least 1 annual cholesterol measurement was only significant in 2005 (LDP 89% vs. Non LDP 79%) and 2006 (LDP 88% vs. Non LDP 79%).

Fig. 6. Evolution in the proportion of patients receiving statin therapy and insulin therapy.



The proportion of patients receiving statin therapy was significantly higher in the LDP group in the years 2005 and 2006 and the proportion of patients receiving insulin therapy was significantly higher in the LDP group in 2006.

Chapter 4: Barriers and facilitators to evidence based care of Type 2 Diabetes patients: experiences of general practitioners participating to a Quality Improvement Program

Goderis G, Borgermans L, Mathieu C, Van Den BC, Hannes K, Heyrman J et al. Barriers and facilitators to evidence based care of Type 2 Diabetes patients: experiences of general practitioners participating to a Quality Improvement Program. Implement Sci 2009; 4:41.

Abstract

Objective: To evaluate the barriers and facilitators to high-quality diabetes care as experienced by general practitioners (GPs) who participated in an 18-month Quality Improvement Program (QIP). This QIP was implemented to promote compliance with international guidelines.

Methods: Twenty out of the 120 participating GPs in the QIP underwent semi-structured interviews that focused on three questions: 'Which changes did you implement or did you observe in the quality of diabetes care during your participation in the QIP?' 'According to your experience, what induced these changes?' and 'What difficulties did you experience in making the changes?'

Results: Most GPs reported that enhanced knowledge, improved motivation, and a greater sense of responsibility were the key factors that led to greater compliance with diabetes care guidelines and consequent improvements in diabetes care. Other factors were improved communication with patients and consulting specialists and reliance on diabetes nurse educators. Some GPs were reluctant to collaborate with specialists, and especially with diabetes educators and dieticians. Others blamed poor compliance with the guidelines on lack of time. Most interviewees reported that a considerable minority of patients were unwilling to change their lifestyles.

Conclusions: Qualitative research nested in an experimental trial may clarify the improvements that a QIP may bring about in a general practice, provide insight into GPs' approach to diabetes care and reveal the program's limits. Implementation of a QIP encounters an array of cognitive, motivational, and relational obstacles that are embedded in a patient-healthcare provider relationship.

Introduction

Landmark studies have demonstrated that intensive management of hyperglycemia, hyperlipidemia, and hypertension significantly reduces morbidity and mortality in patients with Type 2 Diabetes Mellitus (T2DM) (1-9). T2DM is a 'silent disease' until irreversible microvascular (*e.g.*, nephropathy, retinopathy, diabetic foot) and/or macrovascular (*e.g.*, myocardial infarction, stroke) complications become apparent. Prevention of these complications rests on timely institution of drug therapy by the prescribing physician, usually a general practitioner (GP), and the patient's compliance with the treatment regimen and willingness to make lifestyle changes. A proactive follow-up of diabetic patients is essential and should include foot examinations, blood and urine tests, and eye examination (10). In addition, patients should be counselled about the dangers of diabetes and the importance of a healthy lifestyle, and impressed with the need for compliance with doctor's orders.

Unfortunately, many patients do not receive such level of care despite the availability of internationally-accepted treatment guidelines describing optimal management of patients with diabetes (11). Optimal use of guidelines in general practice demands specific implementation strategies aiming at the reduction of barriers to high-quality care (12). However, a clear understanding on how to overcome these barriers seems to be lacking (13-15), despite previous studies which outlined the obstacles that prevent GPs from following the guidelines (16-24). Our study reports on 20 GPs who participated in an 18-month Quality Improvement Program (QIP). The aim of this program was to improve diabetes-related patient outcomes through the implementation of evidence-based guideline recommendations. The different interventions of this QIP are described in the Appendix. The program resulted in significant improvements over time of HbA1c (-0.4%, CI 95% (-4;-3)), systolic blood pressure (-3 mmHg, CI 95% (-4;-1)) and LDL-C (-13 mg/dl, CI 95% (-15;-11)). However, results widely varied between participating GPs. Accordingly, we conducted a complementary, qualitative study (January to April 2008) nested in the controlled trial, to gain better insight into what changes the GPs had actually experienced. To fully understand these changes, we relied on an 'implementation model' based on the one described by Grol *et al.*, 2004 (25-27).

Methods

We conducted this qualitative research to acquire a better understanding of the barriers to high-quality diabetes care and into the mechanisms of change that eventually were induced by the QIP according to the experience of participating GPs. We opted for 'one-on-one' interviews in order to investigate the perceptions of the GPs about the QIP that essentially targeted the individual GP. We opted for semi-structured interviews in order to let the interviewees talk freely, as well as to deepen the interviewees' personal feelings about both the experienced barriers to high-quality care and facilitators of change.

To gain maximum information, the interviewees were randomly chosen from a stratified sample of participants according to clinical performance scores before and after the intervention. The clinical practices were divided in four strata relying on baseline performance (stronger versus weaker) and on the degree of improvement during the project (modest versus substantial). A researcher not involved in the interviews randomly chose five GPs within each stratum. If a selected GP refused to participate, the next GP on the list in that stratum was invited.

Interviewees and interviewers were blinded to the practice stratum at the time of the interview. Our design called for 20 interviews with *post-hoc* analysis and evaluation of data saturation. Plans were made for additional interviews if the data saturation criterion was not met. Three main questions were asked in the semi structured interviews: 'Which changes did you implement or did you observe in the quality of diabetes care during your participation in the QIP?' 'According to your experience, what induced these changes?' and 'What difficulties did you experience in making the changes?'

Subsequent discussions delved deeper into these topics by using an adaptation of 'reflective listening', a counselling technique that elicits a thorough disclosure of the interviewees thoughts and feelings (28). It involves reflecting back to the interviewee what the interviewer believes was said in order to verify or clarify the interviewee's statements, and encourages interviewees to continue elaborating their views. In our

interviews, not only were the assertions reflected back, the interviewees were also actively confronted with eventual inconsistencies in their answers. Throughout, the interviewers provided reassurance by intonation and body language in order to disclose the very personal feelings and experiences of the interviewees.

The interviews took 30 to 45 minutes and were conducted individually by two experienced researchers (GG and LBO), one a practicing GP and the other a community nurse specializing in health care consultancy. All interviews were taped and transcribed.

Before analyzing the transcripts, we discussed the analytical method to use. We decided to categorize the items by theory-based deduction using the 'implementation model' (Grol *et al.*, 2004). We chose this model because it is based on a comprehensive overview of theories on implementation and behavioural change. These theories relate to the individual's cognitive, educational, and motivational attributes, as well as social, organizational, and economic factors. This model also reflects the basic structure of the interviews: barriers and facilitators of guideline implementation are well-described. As such, this model allows for deductive coding and categorizing of the items according to the level of action. After a first discussion round, we reached consensus to categorize the items in three levels: individual GP, individual patient, and social interaction, context, and organization. Items were divided into 'barriers to high-quality diabetes care' and 'factors facilitating change'. Barriers at the individual level were further categorized into subcategories of 'knowledge', 'awareness', 'attitude and motivation', 'routine' and 'others'. All transcripts were re-read when necessary and independently analyzed by GG and LBO to ensure reliability of the data. Transcripts were manually coded and the items were categorized using Microsoft Excel spreadsheets. Differences in coding were discussed and final decisions on items and categories were based on a consensus between the two interviewers.

Results

Two GPs refused to participate in the interview and were replaced by the GP next in line. In a post-hoc analysis, we found that few new themes were emerging after about 17 interviews, making it unnecessary to continue the interviewing after the 20 initially planned interviews. Table 1 shows the main characteristics of the interviewees that were felt to be typical of all 120 participants in the QIP. Table 2 shows the results of itemization that was obtained in commons consensus by the two researchers.

All but four of the GPs confirmed the importance of improved adherence to the evidence-based guidelines. The four GPs who did not experience improved adherence belonged to a stratum with a stronger baseline performance, and three of them also belonged to the stratum with weaker improvement during the project. Three of them revealed that they had previously followed an intensive course on diabetes management. The fourth GP is still collaborating with the medical faculty of the university. Most interviewees also reported improvements in follow-up procedures, evidence-based drug prescription practices, and referral rates. The more frequent follow-up visits included regular blood monitoring and general screening for complications. Several GPs mentioned better recordkeeping.

Implementation of evidence-based treatment was evident in more timely adjustments in therapy if target criteria fell short, and in greater attention to cardiovascular risk factors, above and beyond conventional glycemic control. Finally, more patients were treated with insulin.

Some interviewees reorganized their practices to better comply with the guidelines. Others instituted regularly scheduled office visits, and some split the visits into two parts: one part dedicated to routine follow-up and the other to discussions of treatment and lifestyle. The interviewees noted better medication compliance and improved adherence to follow-up schedules by the patients.

Barriers to high-quality diabetes care and factors facilitating change

Our analysis showed that a first barrier to successful diabetes care was GPs inadequate knowledge how to manage insulin therapy and cardiovascular risk.

> *'My attitude about insulin therapy onset has changed. Before the start of the project, I tried too long oral anti diabetics, but the courses have changed my attitude. I became confident in starting insulin therapy, whereas before I would never initiate insulin therapy. (12-S3)*

A second barrier was the GPs' lack of awareness of their own performance because of 'blind spots'.

> *'Such a project with follow-up is important because it obliges you to question yourself. I thought my patients were reasonably well controlled, but the QIP—especially the feedback—makes you confront your problems and weaknesses.' (3, S1)*

Several interviewees also affirmed that before the start of the project they did not truly understand the importance of attaining clinical targets and regular follow-ups.

> *'The constant support and the organized courses made the difference. The protocol map, which has become a reference work, also contributed a lot. Because of the feedback, I became aware that my performance on lipid-lowering therapy was not good. This, together with information on vascular pathology as a major problem in diabetes, made me change my attitude. I have begun to prescribe more statins.' (10-S3)*

A third barrier, expressed by several interviewees, was the presence of scepticism about evidence-based treatment and of collaborative care, and their concerns about losing control and sanctions that may result from diabetes care improvement plans.

- *'I do everything myself. I find it difficult to work in a team, and I am rather sceptical about the 'soft sector' (psychologists, educators…)' (11-S3)*
- *'Policymakers should use such programs for positive motivation. They should not connect results with negative implications (e.g., loss of accreditation).' (15-S3)*

Some GPs considered evidence-based medicine (EBM) only as background information describing the ideal situation to strive for, but not as a stringent, compulsory framework.

> *'Paper is no reality. EBM is only a support tool, but can never be an imposed framework.' (3-S1)*

One GP admitted that he had worked according to a fundamentally different paradigm closer to alternative medicine. From this viewpoint he disagreed with the guideline on many aspects, such as the importance that was given to lipid control.

> *'Evidence-based medicine is a relative term…something might be evidence-based, but I have in mind other parameters that are much more important. In my alternative point of view, I do not care a lot about cholesterol, for example.' (7-S2)*

Some GPs admitted being lax and several indicated that lack of time—because of suboptimal practice management—prevented them from providing good quality care.

- *'I admit that I was lax before, but have changed during the project. Some patients were incredibly surprised that finally they were getting good care.' (7-S2)*
- *'I didn't observe major behavioural changes in most patients, but this may be associated with my own passive attitude. I made no changes in my organization of care and I did not spend enough time at it.' (16-S4)*

Several GPs also questioned the feasibility and desirability of implementing these guidelines in an older diabetes population.

- *'Many of my patients are older than 80. I will not forbid them to eat a piece of cake. Indeed, my own attitude towards elderly people is a little bit more loose.' (4-S2)*
- *'The recommendations on weight loss and physical activity are useless for a lot of elderly people who are too ill or immobile to follow them.' (3-S1)*

Factors conducive to good care were also discussed. The consensus was that transparent treatment protocols and tailored post-graduate courses would go a long way in overcoming knowledge gaps. Benchmarking feedback confronted the GPs with their blind spots and weaknesses, and increased their awareness of shortcomings in their case management habits. Case coaching was identified as an important innovation in improving 'knowledge on the spot', especially in initiating and adapting insulin therapy.

'The extra coaching was unique to this project and functioned like clockwork. You only had to make a phone call—that is very comforting to a GP.' (12-S3)

Several GPs confirmed that the three-month data collection exercise encouraged regular recordkeeping and a structured approach to patient follow-up.

'The imposed recordkeeping of patient data put me under some pressure. Imposing a structure helps you handle your job more systematically. Since the project has stopped, this disciplined approach is beginning to wane again.' (1-S2)

Many GPs also felt that care was compromised by the patients' insufficient understanding of diabetes, lack of awareness of serious complications, and of the importance lifestyle changes. Fear of insulin therapy ('fear of the needle') was also mentioned. However, these barriers were perceived as something that could be overcome by education, especially when provided by well-trained nurse educators.

'The big change is the availability of the nurse educator… She really took the time to explain the problem of diabetes. People have a better understanding of what HbA1c is…people are afraid of needle sticks and this fear has decreased because of the project, thanks to the nurse educator.' (2-S2)

GPs also described the synergistic effect of several healthcare workers delivering the same message in inducing a sudden change in attitude.

'If three professionals give the same message and if, moreover, patients receive the same message by television, and then a sudden change can occur.' (8-S1)

There was consensus that patients' attitudes and lack of motivation are major barriers to implementing evidence-based treatment, especially when it involved a change in lifestyle.

'Physical activity and weight control remain the main problems. The motivation to change lifestyle habits is often completely absent. Some patients deny the problem: 'I don't eat very much'. (9-S2)

Finally, GPs felt that about one-third of the patients would be uncooperative no matter what changes were proposed, and most GPs agreed that changing entrenched lifestyle habits was difficult for most patients to achieve, whatever their

initial motivation. For the most part, any such changes would be small and temporary.

> *'A minority—about 30%—doesn't want to hear anything. They won't even go to see the nurse educator. Another 30% are somewhat motivated, but not too much, and the remaining 30% really cooperate. The added value of the project, probably, applies only to patients who are motivated and who can get motivated.' (2-S2)*

GPs also mentioned social, organizational, and legal barriers and facilitating factors. The interaction between a GP and his or her patients, especially when it concerns a long-term relationship, can itself hamper the transition to high-quality diabetes care. Several GPs described how patients were accustomed to certain situations and habits of their GPs, *e.g.*, a limited use of drugs. They did not always understand or appreciate the sudden change in their GP's attitude; this led to tensions in some cases and loss of contact in others.

- *I have started prescribing lipid-lowering drugs relatively recently. Before the project, I was rather reluctant to prescribe medications and my patients were not accustomed to my new attitude. So, I had to take a gradual approach.' (10-S3)*
- *'Previously, some patients probably consulted me because I was easygoing. Since my participation in the project, I've pushed them more and so I lost two patients. They frankly told me 'We're leaving because you exaggerate things. What's the matter with you?' But patients and physicians must evolve together, although at a moderate pace.' (7-S2)*

However, the project mitigated such unfortunate instances through counselling sessions involving the GPs, patients and nurse educators. The net effect was a strengthening of the physician-patient relationship and a motivational boost to the latter.

'Diabetes patients themselves feel much more appreciated; because of that, the link between us and our patients has strengthened.' (17-S4)

Most GPs held that a lack of a clear delineation of responsibilities leads to competition between the GP and the specialist, with the latter being perceived as holding the upper hand. This competition is reinforced by the skewed reimbursement schemes in Belgium in favour of the specialist concerning patient education and home blood glucose monitoring (HBGM) kits. This skewed situation was considered as an important factor that prevents many GPs from commencing timely insulin therapy.

> *'Specialists gain too much control of referred patients and often exclude GPs from direct patient care. This is especially true of patients on insulin who get free instructions and monitoring kits at the diabetes centres, unlike patients in primary care. So, it's nearly impossible for GPs to hold on to patients on insulin.' (1-S2)*

The QIP redefined the GP as a central 'manager' with explicit responsibilities for the care for patients with diabetes.

> *'To summarize this project: we started with a good protocol and established better channels of communication between primary and specialist care.…The delineation of responsibilities and degree of familiarity among the partners were very important in making it easier to me to refer more patients.' (14-S1)*

This was much appreciated by the interviewees. It reinforced the GPs' feeling of recognition, boosted self-esteem, promoted a greater sense of responsibility, and improved their professional relationships with specialists.

> *'The project did not merely create the illusion that the GP was pivotal in diabetes care, he or she actually became the central figure and this fact increased their job satisfaction.…This only became possible because of an attitude change on the part of the endocrinologists. Now they say 'you GPs have to do the job, but call me when necessary.' This is a big change from the usual 'let us do our work; after all we are the specialists and you may help a little bit'. We collaborate as one team—there's mutual support! We're on the same wavelength and feel we work together toward the same objectives.' (13-S4)*

Many GPs regarded the role of the nurse educator as complementary to their own and, feeling that they themselves lacked the requisite skills and time, were relieved to relinquish patient education to them.

> *'I prefer to have the nurse educator bring up insulin therapy before I get to it.…After 30 years in general practice, I'm somewhat hesitant to get into a protracted struggle with patients to try to convince them of the need for insulin. 'If you're not interested, so be it,' I think by myself. The nurse educator is an invaluable asset in such cases.' (8-S1)*

One GP felt that the Belgian fee-for-service scheme was an important impediment to the delivery of quality care, explaining that a pay-for-performance system would be a better motivator. In addition, direct payment by patients was also seen as a significant factor that discouraged patient referrals and HBGM necessary to evaluate insulin therapy.

Discussion

Previous studies have disclosed a significant gap between the quality of diabetes care commonly encountered and recommended evidence-based guidelines (14). To date, most research on barriers to and facilitators of high-quality care has been done before the start of improvement programs. Our study was based on interviews with GPs who actually participated in a project aimed at optimizing diabetes care. This approach, combined with the 'reflective listening' technique, elicited disclosure of very personal feelings and experiences related to changes in performance. As such, qualitative research nested in an experimental trial may clarify the improvements that a QIP brings about in a general practice.

The primary finding was that the project accomplished more than merely improving the quality of care. It also impacted the emotional and motivational status of the GPs. Previous focus group-based research had revealed that GPs working in the 'usual' setting in our country felt frustrated, partly because they felt inferior to specialists (29). We showed that role-redesign and delineation of responsibilities *vis-à-vis* the specialists enhanced a GP's self-esteem and sense of responsibility. All interviewees were unanimous that this project was very beneficial because it added value to their

jobs, even though some were concerned that QIPs could have manipulative ends or lead to sanctions.

Second, most of the GPs reported a major improvement in their diabetes care. According to the theory of planned behaviour, decisions are made according to personal models and beliefs about the changes about to be made, and the perceived benefits and risks associated with them (30). Several GPs indicated that the changes resulted from a conscious decision based on interconnected key elements during the quality improvement process. Reported key elements were the need to keep up with knowledge, the increased awareness that their practice needs improvement, and that their attitude needs adjustment. The GPs also observed attitudinal changes in their patients, *e.g.*, better adherence to drug regimens and follow-up visits.

Third, a multifaceted QIP may evoke complex changes that go beyond individual physicians and patients, because they form an interconnected and interdependent social continuum. The GPs described cases in which joint and coherent actions of several health workers effected a change in a patient's attitude where a solitary GP failed. The QIP facilitated patient referrals to the nurse educator, despite certain resistance on the part of some patients or physicians. The nurse educator, in turn, contributed to patient care by ensuring follow-ups, providing information on insulin therapy and health lifestyles, and performing complementary examinations, *i.e.*, carrying out functions for which the GP lacked time or did not possess adequate skills or motivation. This task delegation allowed the GPs both to sustain their ongoing relationship with the patients and to concentrate the efforts on their essential tasks, which are the medical management and follow-up of diabetes.

Finally, the QIP also altered interpersonal relationships. Most GPs confirmed that the QIP strengthened their relationships with their patients and improved communications with specialists and other healthcare providers. They also perceived a change in attitude on the part of the endocrinologists toward them, which markedly enhanced the GPs' motivation and sense of responsibility. These findings substantiated various theories and research findings that a positive relationship among healthcare providers is an important component of high-quality patient care (31; 32).

Nevertheless, limitations of the QIP were also described. First, according to the interviewees, a significant minority of patients remained refractory to change, with many refusing to see a nurse educator. Most patients found it difficult to change their lifestyle, and even in the case of motivated individuals the changes were often minimal and temporary. These findings confirm previous findings that sustainable lifestyle changes are hard to implement in clinician-centred models of patient education (18;33-35). Moreover, these models are labour- and resource-intensive (36) and traditionally put the emphasis on imparting knowledge (37). Yet, in even the most successful trials of face-to-face education, many participants are not willing or able to attend the sessions (38;39). Therefore, ongoing research evaluates the effect of new models that are based on peer support. These models put the emphasis on coping with illness, rather than managing it (40). Peer support seeks to build on the strengths, knowledge and experience that peers can offer. Greenhalgh *et al.* has tested the effect of a narrative method (a person telling a story) versus conventional nurse-led education in a minority ethnic group of people with diabetes (40). The results show that unstructured storytelling is associated with improvement of patients' enablement and comparable changes in biomedical markers. Other self-management programs evaluate the effect of other peer support interventions, like telephone counselling or web-based peer support. Future QIPs may incorporate peer support interventions replacing or complementing the traditional clinician-centred patient education interventions.

At GP-level, four interviewees affirmed not having experienced a major impact of the QIP on their quality of care. In fact, they experienced the QIP somehow as superfluous because they already paid special attention to evidence-based diabetes care before the start of the project. The study also revealed that some GPs were reluctant on to reorganize their practices to comply with the project's requirements, or even to find the time for efficient patient follow-up. Accordingly, future QIPs should specifically address such issues. Moreover, while the project was indeed able to induce a change in attitude with regard to medical diabetes treatment, some other deeply rooted attitudes were more difficult to change. For example, several GPs asserted that nurse educators and other personnel in the so-called 'soft sector' are of little value in good diabetes care. Collaborative shared care with specialists also remains a concern, despite the improvement that was observed during the project.

One GP reported persistent problems with one local endocrinologist who was blamed for his disdainful attitude to general practice. Other GPs described minor remaining difficulties with endocrinologists despite overall satisfaction with the arrangements. These findings complement previously reported difficulties in collaborative shared care. One of the major reported issues about shared care is the problem of suboptimal communication between the involved providers (41). This problem is associated with discontinuity in care and lower quality of care (42). Other problems are related to lack of clear division of tasks and responsibilities between the involved providers, eventually leading to overlap and competing interests (29;43). Despite these problems, we think that shared care is necessary to guarantee high-quality diabetes care because the management of this disease is too complex and too broad to have it provided by one person. However, the aforementioned problems are a real point of concern. Moreover, as our research shows, providers are not always willing to collaborate. Thus QIPs should pay special attention to eventual relational problems, to communication issues and to the distribution of rights, responsibilities and tasks between patients, GPs, nurse educators and specialists.

The role of EBM in daily practice remains a point of controversy. While many GPs accepted the existing guidelines, some did not. Some GPs fundamentally disagreed with EBM. Others accepted EBM as background support, but were afraid that EBM would be used to impose coercive instructions for daily practice. Several GPs questioned the feasibility and desirability of the American Diabetes Association guideline-based recommendations in the elderly or immobile people. Indeed, elderly patients are particularly sensitive to the adverse effects of drugs and polypharmacy, putting constraints on the classic diabetes treatment. In particular, hypoglycemia is an important topic in the diabetes treatment of elderly people. Recent studies (44;45) clearly indicate that hypoglycemia may be a contributing factor to morbidity and mortality in older patients. As such, strict adherence to guidelines for younger patients could be deleterious for the frail elderly (46). Geriatric guidelines on the management of Type 2 Diabetes accentuate that treatment should be holistic, targeting all important aspects of the geriatric patients with priorities in the treatment scheme. Diabetes-related targets should be individually adapted to the frail patients with special attention to avoidance of side effects (47-49).

This qualitative research presents some limitations. A first possible bias concerns the researchers who conducted the interviews. They were previously involved in the QIP, and thus they are known by the interviewees as promoters of this program. As a consequence, GPs in disaccord with some issues of the QIP-process may have been discouraged to mention them. The GP cohort selected for the study represented an additional limitation. The participants were part of a larger sample of volunteer GPs who were particularly interested in the project. This selection bias may well be reflected in their answers. In order to generate a broad spectrum of answers regarding barriers to change, we employed a targeted sampling procedure that took into account the performance of the GP's practice. Only their subjective feelings and views are covered here, although a more balanced picture would have emerged if a joint patient-provider perspective had been offered. It remains for future research to include interviews with patients and, perhaps, employ mixed focus groups, and audio- or video-record observations of the clinician-patient encounters. However, despite the possible bias, we feel this qualitative study has provided a very balanced overview of the QIP's strengths and weaknesses, and validated the quantitative findings that had been obtained.

Implications

Previous research revealed numerous barriers to high-quality diabetes care at the level of provider, patient, and healthcare organization. However, most of this research was done outside the context of quality improvement. Our research reveals the viewpoints of physicians who experienced a quality improvement process and it allows for evaluating the complex interactions between barriers and facilitators during this process. It has become obvious that implementation of a QIP encounters an array of cognitive, motivational, and relational barriers that are embedded in a patient-healthcare provider relationship. As their success may depend on overcoming key barriers, QIPs should incorporate mechanisms to actively detect and overcome these barriers or to cope with them. Moreover, several barriers appear to be interdependent, developing several ‘chains of barriers’. This phenomenon may be a reason why multifaceted QIPs acting on different barriers in a chain are likely to be more effective than single interventions.

Our research particularly revealed the GPs feelings on collaborative shared care. While some of them disagree on the added value of diabetes educators, many GPs feel some uneasiness regarding the competition with specialist care. These feelings may be reinforced by the typical Belgian healthcare setting, but we believe that they are the expression of a very human nature and thus not unique to the Belgian situation. Literature on this issue, however, is very scarce. Our research also showed that these negative assumptions and feelings can be overcome by paying attention to them and by enhancing the personal contact and communication between the people involved.

The interviews also revealed the limits of a clinician-centred model of patient education and self-management, and confirmed the quantitative results of the study on this issue. Future QIPs could incorporate and test innovative patient-centred methods, like different models on peer support for patients.

Finally, several interviewees reported real concerns on the applicability of the 'traditional' diabetes guidelines in a subset of the patient population, namely the elderly. These concerns have been joined by specific geriatric guidelines. These findings show that quality improvement is not a unidirectional process from guideline to practice. Often, several practitioners express the same difficulties with implementing a guideline. In that case, it might actually reveal a flaw in that guideline rather than a barrier related to the practitioners. And thus QIPs should also be used as instruments to test the feasibility of guidelines as well as to highlight any flaws.

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Table 1. Principal characteristics of participating GPs.

	S1 (N = 5)	**S2** (N = 5)	**S3** (N = 5)	**S4** (N = 5)	**All interviewees** (N = 20)	**All participants** (N = 120)
Mean age (years)	46	45	48	36	44	44
Females (N)	1	1	1	3	6	45%
Workplace						
Solo practice (N)	3	3	0	1	7	38%
Two man practice (N)	0	2	3	1	6	32%
Group practice (N)	2	0	2	3	7	30%

S1 = Stratum of GPs with weaker baseline performance and modest improvement during the QIP
S2 = Stratum of GPs with weaker baseline performance and substantial improvement during the QIP.
S3 = Stratum of GPs with stronger baseline performance and modest improvement during the QIP.
S4 = Stratum of GPs with stronger baseline performance and substantial improvement during the QIP.

Table 2. Coded categories and themes

Perceived barriers to optimal diabetes care		
Level	**Factor**	**Item**
Physician	Lack of knowledge on	- global cardiovascular treatment beyond glycemic control - insulin therapy
	Lack of awareness regarding	- personal practice performance ('blind spots') - need to reach treatment targets and regular follow-up
	Attitude and motivation	- laxity regarding treatment targets and timely follow-up - attitude to polypharmacy - scepticism regarding evidence-based treatment, top-down quality improvement projects and shared care collaboration
	Practice organization	- lack of scheduled visits, lack of planned follow-up, lack of support staff
Patient	Lack of knowledge	- insight regarding complications, significance of HbA1c
	Lack of awareness regarding	- personal dietary patterns - personal health status (HbA1c, blood pressure, cholesterol)
	Attitude and motivation	- fear of insulin treatment - lack of motivation for follow-up or to change lifestyle
	Routine behaviour	- maintaining lifestyle change very difficult - adhering to planned follow-up visits is difficult
	Age and co-morbidity	- too strict control can be dangerous in older patients - immobility hampers physical exercise and shared care referral
Context/or-ganization	Relationships	- between GPs and patients (inertia to change) - competition between specialists and GPs
	Lack of teamwork	- Need for clear description of each provider's duties and responsibilities - Need for identical messages to the patients from all health care providers
	Financial barriers	- out-of-pocket payments for education, dietary advice and HBGM material - skewed reimbursement of HBGM material - fee for service: this system doesn't motivate GPs to deliver high-quality care

Perceived change facilitators	
Level of impact	**Item**
Physician	Treatment protocol and post-graduate education; Benchmarking feedback Case coaching; Timely data collection Increased contact and communication with peers in other disciplines Participation in team meetings Attitude change on the part of specialists
Patient	Nurse educator and IDCT working as a team Free services and free materials Identical messages from different sources (GP, specialist, educator, television Attitude change on the part of the GP
Context and organization	Role redesign and reassignment of responsibilities Serial removal of barriers Task relief

HBGM = Home Blood Glucose Monitoring; IDCT = Interdisciplinary Diabetes Care Team (endocrinologist, nurse educator, dietician) installed at the primary care level

Appendix: Interventions of the Quality Improvement Program

Interventions in support of the GP

- **Diffusion of a Evidence-based treatment protocol with clear recommendations on:**
  1. Timely follow-up (every three months), with attention to all important parameters (biological risk factors and early signs of complications).
  2. Global treatment with attention for:
     a. Glycemia control, blood pressure control and blood lipids control.
     b. Comprehensive treatment.
        i. Healthy lifestyle habits.
        ii. Comprehensive drugs treatment including anti-platelet therapy, BP treatment with ACE-inhibition, and statin therapy.
  3. Target-driven treatment (7% for HbA1c <7%, SBP ≤130 mm Hg, LDL-C <100 mg/dl) with treatment intensification whenever the targets are not reached.
  4. Task description:
     a. The GP receives the overall responsibility for the management of diabetes patients. If the GP does not succeed in reaching the targets, he or she can call for help by referring to partners in the diabetes care (interdisciplinary diabetes care team, or IDCT, or hospital-based diabetes clinics).
     b. The IDCT functions in support of the GP whenever treatment targets were not reached.
     c. The hospital-based diabetes clinic should treat patients with case of complications and with complex insulin therapy schemes.
- **Clinician education and coaching**
     a. postgraduate educational sessions on:
        i. the evidence-based treatment of T2DM patients, according to the treatment protocol, with special attention to the principles of global cardiovascular treatment and the target driven approach.
        ii. the initiation and adjustment of insulin therapy in general practice.
     b. Case coaching by the endocrinologist: the GP can call for help by mail or by phone regarding treatment schemes of individual patients without referring them to the specialist.
- **Feedback:** benchmarking feedback: each GP receives feedback on the treatment schemes and on the outcomes of patients of his or her practice in comparison with the results of the entire group.
- **Incentives:** €60 for each included patient; involvement of opinion leaders (endocrinologist from the University Hospital)

Interventions in support of the patient

- **Availability of patient education** by a nurse educator, a dietician, or a general internist working together in one IDCT, upon referral by the GP
- **Availability of Home Blood Glucose Material** for patients with insulin therapy initiated by the GP and the IDCT

Organizational interventions

- **Team changes:** the IDCT was newly created and acted on the interface between primary and specialist care. The team consisted of a general internist, a diabetes educator (this intervention is innovative in Belgian primary care) and a dietician. It could only be counselled upon referral by the GP and was supervised by the endocrinologist of the hospital-based diabetes clinic and her team trough bi-monthly joint team meetings.
- **Timely data collection:** GPs are asked (by mail and by phone) to deliver diabetes related patient data every three months.
- All interventions as well as all communication processes were implemented and guided by a 'program manager'.

IDCT = Interdisciplinary Diabetes Care Team (endocrinologist, nurse educator, dietician) installed at the primary care level

Chapter 5: Monitoring Modifiable Cardiovascular Risk in Type 2 Diabetes Care in General Practice: the Use of an Aggregated z-score.

Monitoring Modifiable Cardiovascular Risk in Type 2 Diabetes Care in General Practice: the Use of an Aggregated z-score. Geert Goderis, M.D.; Liesbeth Borgermans, Jan Heyrman, Carine Van Den Broeke, An Carbonez, Chantal Mathieu, Geert Verbeke, Richard Grol. Accepted for publication in 'Medical Care' (20/12/2009)

Abstract

Background: Since many patients in usual care reach the diabetes treatment goals, it may be more efficacious to focus quality improvement efforts on those general practice populations requiring additional support. We therefore developed a tool based on a composite endpoint considering blood pressure, lipids and glycemia.

Methods: We created an aggregated z_A-score, calculated as the average of three z-scores testing whether the mean practice values of HbA1c, LDL-C and Systolic Blood Pressure (SBP) are significantly higher than the corresponding ADA-target (respectively 7%, 100 mg/dl and 130 mm Hg). This score was used with 100 general practices who participated in a Quality Improvement Program (QIP). We defined the cut-off value (COV) to determine 'Practices Requiring Support' (z_A < COV) using a Receiver's Operating Characteristics curve with the mean practice CHD risk as gold standard. To further test the z-score validity, we calculated the correlation coefficient between the z-score and the mean practice CHD risk and the improvement in the z-score after the QIP.

Results: The COV was -1.22 and was valid to discriminate between practices at higher risk from practices at lower CHD risk (24±4% vs. 19±4%). The correlation coefficient was -0.515 ($p=0.001$). The average z-score increased from -1.21±0.97 at baseline to 0.49±1.01 after the intervention ($p<0.001$).

Conclusion: This scoring system is useful to picture practice populations with diabetes who are at high cardiovascular risk due to modifiable risk factors. While the unadjusted z-score cannot be used to compare physicians, this technique can be used to evaluate improvement efforts over time.

Key words: diabetes, quality measurement, cardiovascular disease, risk assessment, general practice

Introduction

Type 2 Diabetes Mellitus (T2DM) is a highly prevalent chronic disease that can lead to serious complications, including heart disease, stroke, blindness, lower limb amputation, kidney failure, disability and premature death (1). There is a sizable gap between the recommended care in general practices and the care patients actually receive (2). Quality Improvement Programs (QIP) are considered as essential to close this gap (3;4). Yet many intervention programs do not succeed, or exert only small improvements (5;6). Moreover, cross sectional studies of the usual care settings indicate that a large part of the patients still reaches the treatment targets (7-13). These data could indicate that "blockbuster campaigns" involving QIP for ***all*** T2DM patients are expected to be less effective because an important number of patients already are on target. It may be more efficacious to focus the quality improvement efforts on those patients who still require additional support. However, we are not aware of any monitoring system that prospectively enables focused quality improvement campaigns.

On the other hand, a wide range of outcome and process indicators exist to evaluate both the quality of care and the physicians' performances (14;15). But the main objective of these indicator sets is to install a system that rewards "good clinical practice". A well- known example of such a rewarding system is the UK 'Quality and Outcomes Framework' (16). However, we think that such a system should at least be complemented by a system that supports practices lacking optimal performance. Practices may have objective problems in reaching high quality care. Some practices can concentrate patients whose diabetes may be difficult to control, others may work in a difficult context, e.g. in a region without the presence of specialized diabetes clinics... Therefore, we propose a monitoring tool that can picture diabetes practice populations who may be in need of additional support. In fact, we propose to monitor HbA1c, LDL-C and SBP at practice level using a z-score for each outcome. In addition, we propose to combine these z-scores into one aggregated score that is an indicator for the mean CHD risk of the practice population, associated with modifiable risk factors.

Methods

Design, setting and statistical analysis

Study data were derived from the "Leuven Diabetes Project" (LDP), a prospective assessment of the quality of care for people with T2DM. The patients enrolled in the study were from the area surrounding the University Hospital Gasthuisberg Leuven in Belgium. Full information on the study design and subject recruitment is available elsewhere (17;18). Data on 2495 T2DM patients were submitted by 108 Family Medicine Practices before the start of a QIP between January and June 2005 (T0). Patient information was also obtained after the intervention between July and December 2006 (T1). The QIP tended to improve patient outcomes, especially HbA1c, blood lipids and blood pressure through support measures for general practitioners and patients. All data were analyzed using SPSS 17 software (SPSS Inc., Chicago, IL USA). For all patients, we calculated the patients' ten year risk of total coronary heart disease (CHD) using the UKPDS risk® engine spreadsheet, a validated risk estimation model (19;20). We then calculated the mean practice CHD risk. In order to compute the individuals' CHD risk, missing values were replaced by the average of two nearby points.

Defining the outcomes for follow-up.

In accordance with the recommendations for the development of quality indicators (4), the metric in this study was developed by a multidisciplinary, balanced consensus group who utilized literature searches and experimental testing. A literature search was performed for diabetes related intermediary patient outcome measures that are indicators of cardiovascular risk and that are sensitive to improvement by medical treatment. Three outcomes met the conditions necessary to be included in the scoring system (HbA1c, LDL-C and Systolic Blood Pressure) because of the following reasons: i. A substantial part of morbidity and mortality in T2DM has a cardiovascular origin (65 to 80% of deaths) (21-23). The UKPDS (24) revealed that increased concentrations of LDL-C, decreased concentrations of HDL-C, hypertension, increased HbA1c and smoking are the major independent risk factors for CHD once diabetes has developed. A Swedish prospective population-based study of 400 patients concluded that inadequate glucose, lipid and hypertension control are predictors of mortality in T2DM patients (25). ii. Blood

pressure, glycemic and lipid levels are most likely to be positively influenced by medical treatment. A large body of clinical trials which evaluated improvements in HbA1c, blood pressure and LDL-C in T2DM patients has shown a reduction in cardiovascular morbidity and mortality (26-28). iii. The three outcomes are available in most electronic medical files and are easily extractable. iv.) HbA1c, Cholesterol and Systolic Blood Pressure are the only outcomes that have been validated as quality indicators for T2DM care (29). v. There is no conclusive evidence that other outcomes, such as body weight and triglycerides, are independent risk factors for cardiovascular disease in a diabetic population. vi. Despite conclusive evidence for other factors, such as smoking and HDL-C, we assumed that the impact that any provider controlled treatment recommended by the actual guidelines can have on these outcomes is not decisive enough to allow for practice monitoring (30).

Construction of the z-scores

Defining the concept

Establishing a z-score is a standard procedure for normalizing aggregated data. This procedure is more useful for comparing practices than comparing the raw averages of HbA1, LDL-C and SBP because practices have different sample sizes and different standard deviations. Moreover, this procedure is necessary to aggregate different outcomes with different measurement units into one combined indicator (31). A z-score comparing a mean value $\overline{X_i}$ to a preset value μ_0 is defined as follows: $z_i = \frac{\mu_0 - \overline{X_i}}{\frac{\sigma_i}{\sqrt{n_i}}}$ where i is the index of practice i. σ_i denotes the standard deviation and n_i the number of patients in practice i. The z-score functions as a one-tailed statistical test. When $\overline{X_i}$ is significantly higher than μ0, with an alpha level of 0.05, then zi<-1.64. As such, for each practice a z-score for the 3 outcomes Hba1c, LDL-C and SBP can be constructed. As values for μ0, we choose the targets defined by the American Diabetes Association (ADA) in 2003 (32): 7% for HbA1c, 100 mg/dl for LDL-C and 130 mm Hg for SBP. Further on, these outcome z-scores will be called z_G for HbA1c (Glucose control), z_C for LDL-Cholesterol, z_B for systolic Blood pressure. The Aggregated practice z-score z_A was then defined as the average of the three outcome z-scores. The z-scores were calculated at the beginning and at the end of

the study for each of the 108 practices but data were only analyzed from practices with 5 or more patients at both time points. To compute $\overline{X_i}$ and σi, case-wise deletion was used for missing variables.

Validation of the aggregated z-score

Valid indicators should show a strong correlation with what they intend to measure ('content validity'). We hypothesized that the aggregated z_A-score is an indicator of cardiovascular risk due to modifiable risk factors. Therefore, there should be a strong correlation between the z_A-score and the mean practice CHD. Moreover, this correlation should be stronger than the correlation of each individual outcome z-score with the practice CHD. We used a single linear regression model to calculate the Pearson's correlation coefficient between the baseline z-scores and the mean practice CHD risk.

Since the value of the z-scores mainly depends on their sensitivity to improvement over time, we also evaluated changes in z_G, z_C, z_B and z_A prior to and after the intervention with a paired t-test. We performed a McNemar test to evaluate whether the number of practices with z_G, z_C or z_B-score< -1.64 significantly changed after the intervention.

The aggregated z_A-score should discriminate between practices with populations at higher cardiovascular risk from practices at lower cardiovascular risk. Therefore, we divided the practices into quintiles according to the z_A-score and we compared the aggregated patient characteristics (mean CHD risk, mean HbA1c, LDL-C, SBP, age, diabetes duration and the proportion of female patients) using a one- way ANOVA technique with Bonferroni post hoc tests.

We calculated the Intra Class Coefficient of the patients' CHD risk for patient populations clustered around the practice using a one- way ANOVA. A large ICC (>0.5) indicates that the variability between the practices is higher than the variability between patients within those practices. As the ICC becomes larger (e.g., > .5), a practice level composite score is a more useful stand alone measure of the practice.

Defining a cut-off point allowing for practice monitoring.

The z_A-score can be used to evaluate practices by ranking them. However, ranking only allows for a relative benchmark evaluation. Yet practices can positively evolve,

even if their position in the ranking list remains status quo. Therefore we searched for a cut-off value (COV) of the z_A-score that allowed us to label those practices with $z_A <$ COV as "Practices Requiring Support" (PRS). The COV was defined using a Receiver Operating Characteristic (ROC) curve. The mean practice CHD risk with cut-off point set at 25% was used as the Gold Standard. The cut-off point of 25% was chosen because it presented the upper quartile limit of the CHD risk in the study sample. The COV of the z-score was defined as the closest point to (0, 1) on the ROC curve, i.e., false positive rate of zero and sensitivity of 100%. After practices had been labelled, they were divided in four groups according to the COV of the z-score (-1.22) and according to the 25% cut-off point for CHD risk (table 3). We then compared the aggregated patient characteristics using a one- way ANOVA technique. We also evaluated changes over time in the number of PRS with a McNemar test.

Results

In the LDP, the mean age of the general practitioners (GP) was 45 years. 45% were female and 38% worked in solo practices, 33% in practices with one other and 29% in group practices with three or more GPs. The number of T2DM patients registered per physician varied from 2 to 73 (with an average of 20 diabetic patients per physician and a median of 19). Most of the GPs working in group practices registered patients individually, but 12 practices grouped all patients. Two practices were lost to follow-up and six others had a patient population < 5 and were excluded. Z-scores at baseline and follow-up were obtained for 100 practices and 2426 patients in total. The patients' mean age at baseline was 68±12 years, the mean diabetes duration was 8±7 years and 51% the patients were female.

Table 1 shows the results of the z-scores at T0 and T1 and the correlation coefficient between the baseline z-scores and the practice CHD. This table shows that each outcome z-score significantly improved after the intervention. Moreover, all outcomes showed a large decrease in the number of practices with a mean value that is significantly higher than the ADA-target (z< -1.64). The correlation coefficient between the T0 z_A and the T0 practice CHD risk was -0.515. This means that the correlation between z_A and the CHD risk was stronger than the correlation of each outcome z-score with the CHD-risk (-0.271 for z_G, -0.403for z_C and -0.308 for z_B). Z_A

improved significantly over time, from -1.21±0.97 at T0 to 0.49±1.01 at T1 ($p<0.0001$).

Table 2 shows the baseline characteristics of the practice populations for all practices, divided according to the quintiles of the T0 z_A-score. The practice CHD risk is calculated at 26%±4% for the first quintile, at 23%±4% for the second quintile, at 22%±4% for the third quintile, at 20%±4% for the fourth quintile and at 19%±4% for the fifth quintile. Differences in CHD risk are significant between the first quintile on the one hand and the 3th, 4th and 5th quintile on the other hand. The Intra Class Coefficient for the CHD risk however is only 0.10, meaning that the variability of CHD risk between the patients in one practice is much higher than the variability between practices.

The COV of z_A used to label practices as PRS was defined at -1.22. The Area Under the Curve was 0.780 ($p<0.0001$, the null hypothesis being that the true area = 0.5). This resulted in a sensitivity of 82% and a specificity of 61%. However, as shown in table 3, 'false positive' practices (group B, N=28) still showed higher values of HbA1c (7.3±0.4%), LDL-C (109±8 mg/dl) and SBP (139±4 mm Hg) but lower values of unmodifiable risk factors, such as age (66±4 years) and diabetes duration (7±2 years). 'False negative' practices (Group C, N=5) on the other hand showed higher values of age (71±4 years) and diabetes duration (9±3 years) and contained more male patients (61%).

PRS (group A and B) compared to other practices (group C and D) showed a significant difference in the mean CHD risk (24±4% vs. 19±4%, $p<0.0001$), mean HbA1c (7.4±0.5% vs. 7.0±0.4%,$p<0.0001$), mean LDL-C (112±8 mg/dl vs. 105±9 mg/d), $p<0.0001$) and mean SBP (139±4 mm Hg vs. 134±5 mm Hg, $p<0.0001$). Almost all PRS (98%) presented with at least one outcome z-score < -1.64, in contrast with 56% of the other practices.

The graphical representation of the z_A-scores allows for the evaluation of the change over time within each individual practice (Figure 1). Only 4 of the 50 practices that were initially labelled as PRS kept this label at T1 ($p<0.0001$). The z_A-score of all but 3 practices improved after the intervention.

Discussion

This paper proposes a tool for the monitoring of patient populations with T2DM in General Practice. The tool is based on HbA1c, LDL-C and SBP, the three principal diabetes related outcomes, all of which are associated with cardiovascular risk and are modifiable via medical treatment. Firstly, we composed a z-score for each outcome. We then aggregated the outcome z-scores into one z_A-score. Each outcome z-score is a statistical test comparing the average of each practice with the corresponding ADA-target. These Z-scores can be used to determine whether the practice mean of HbA1c, LDL-C and SBP is significantly higher than the ADA-target. The z-scores take into account the number of patients in each practice. High volume practices with a high mean HbA1c, LDL-C or SBP are considered a bigger problem than smaller volume practices with similar mean values. The z-score also takes the practice variability into consideration, which means that with equal mean values, a better z-score indicates that more patients are closer to the ADA-target.

The choice of HbA1c, LDL-C and SBP was not arbitrary. Previous research has validated HbA1c, SBP and LDL-C as reliable outcome quality indicators for diabetes care (29). The three proposed patient outcomes are easily extracted from the electronic medical files. Moreover, standardization of the laboratory results enables the possibility that LDL-C and HbA1c measures are free of intra- or inter-observer variability. The recent consensus on the standardization of HbA1c supports the reliability of national and international comparisons of HbA1c measurements (33). The reliability of the SBP value depends on the physician even though recommended procedures exist to reduce variability (34). We decided not to incorporate other outcomes such as HDL or smoking status because these outcomes have not yet been validated as quality indicators. However, when necessary, the concept of the aggregated z-score is flexible and is fit for extension to other outcomes.

The aggregated z-score (z_A) offers some supplementary advantages. The score has shown to discriminate practice populations at higher cardiovascular risk from practice populations at lower cardiovascular risk. Using a COV of -1.22 the z_A-score allows for highlighting practices that may require supplementary support ("Practices Requiring Support"). As such, practices labelled as PRS contain patients at high cardiovascular risk due to modifiable risk factors. It is of utmost importance to improve those risk factors in these highlighted populations. Such practices could

benefit from special quality improvement interventions or from a more profound audit, because they can uncover eventual barriers preventing optimal quality of diabetes care. The individual outcome z-scores (z_G, z_C and z_B) and the aggregated z_A-score are complementary tools. For all practices, each outcome z-score is a monitoring and feedback tool for respectively HbA1c, LDL-C and SBP. For those practices that are labelled as “PRS”, the individual outcome z-scores can further detail the nature and extent of the diagnosed problem. The set of z-scores however cannot simply replace the monitoring of individual patients. The small ICC of the CHD risk indicates that patient variability is much higher than practice variability. Thus, besides the z-scores, a second system monitoring the individual patient values of HbA1c, LDL-C and SBP should exist in order to designate patients at high risk, even in those practices not labelled as PRS.

As z-scores standardize ‘raw’ average values, they are often used in medical literature for biometric measures (like length, weight and BMI (35)), for scale-tests (36) and for technical procedures, such as bone density measurement (37). However, although the z-score procedure is mentioned as a standard procedure in the construction of composite quality indicators (31), it is hard to find examples of such a use in the medical literature. When used for quality purposes, z-scores are applied to control the quality of laboratory or other technical measurements (38;39). We found one article referring to the use of a z-score to measure the quality of ECG reading (40) and we found none on its use for quality assessment in General Practice.

In the recent past other composite quality indicators for diabetes care in General Practice have been proposed. De Berardis et al. investigated whether a composite quality score was able to predict the development of cardiovascular events in patients with Type 2 T2DM (41). The score was calculated using process and intermediate outcome indicators (HbA1c, blood pressure, low-density lipoprotein cholesterol, micro-albuminuria) and was associated with long-term outcomes. However, in our opinion, micro-albuminuria should not be used as an outcome indicator. The test is prone to false positives and needs to be repeated to confirm the diagnosis. Additionally, micro-albuminuria cannot necessarily be removed by medical treatment.

Kaplan et al. recently proposed an aggregate process and outcome indicator to measure the physicians' performance (15). This composite indicator aims to evaluate practices and to assess the physicians' performances, whereas the z-score should be used to monitor the practices. Even if the z-score allows for the ranking of individual practices, it cannot be used to evaluate the performance of individual physicians due to the fact that it has not been adjusted for case-mix factors. No judgment can be made on the provider's performance, since factors such as geographic region, patients' ethnicities, (8;42-44) duration of diagnosis, (45) readiness to change (46), personality traits (45) and psychological co-morbidities (47) may also explain why target levels were not achieved. Given these facts, the z-score is an indicator of the performance of the "practice (patient-physician)" entity, but not of a single physician's performance. It should be noted that an indicator which takes into account patient's case-mix factors would lose its validity as an indicator of patients' cardiovascular risks. Such an indicator would not support our aim of monitoring practice populations with a high but modifiable risk of cardiovascular events.

It is possible to construct alternative z-scores. Initially, we constructed a composite z-score that was based on the number of patients who had reached predefined targets for each outcome. However, the correlation of this target- based z-score with the mean practice CHD risk was only -0.314. It is also possible to define other values for μ0 for HbA1c, LDL-C and for SBP. Again, these exercises resulted in weaker correlations with the mean practice CHD. Finally, it is possible to construct a weighted z-score. The weighting coefficients can be determined by a linear regression model with CHD as a dependent variable and HbA1c, LDL-C and SBP as independent variables. However, the correlation coefficient between the weighted z-score and the mean practice CHD risk was only slightly higher (-5.33). The weighting was based on the specific cohort of the LDP which could eventually lead to problems of generalizability. Therefore, we decided to present the unweighted score.

One limitation of this study is that the z-score was constructed and validated using a data cohort that was collected in an experimental setting. Further validation should be achieved by applying the z-score to other cohorts in several countries. A longitudinal follow-up of practices and patients could also validate the z-score for hard endpoints, not just by calculating the risk of cardiovascular events.

In conclusion, we hereby propose a rather innovative concept in the quality approach of diabetes care. We propose a monitoring system that proactively allows for highlighting practices with patient populations who are at high cardiovascular risk due to modifiable risk factors. This tool can be complemented by a system monitoring the individual patient data. Such a combined system would be a powerful tool to assess those patient populations requiring additional support in order to improve their health status. As such, it would enable the implementation of Quality Improvement Programs that are focused on those patients who require improvement. In addition, the z-score system can be used to assess progress over time, to evaluate the impact of quality improvement efforts, to facilitate communication with the general public and to improve the transparency in diabetes care (31).

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Table 1. This table indicates the values of the mean z-scores for glucose control (zG), cholesterol control (zC), Blood Pressure control as well as the mean values of the average z-score (z_A) at baseline (T0) and after the intervention (T1); the correlation coefficients between the baseline outcome z-scores and the baseline practice CHD risk and the number of practices with z-score < -1.64 at the T0 and T1.

N=100	z_G	z_C	z_B	z_A
Average value at baseline (T0)	-0.48±1.39	-1.33±1.53	-1.81±1.63	-1.21±0.97
Pearson's correlation coefficient between baseline z-score and baseline CHD risk	-0.271	-0.403	-0.308	-0.515
Average value at the end of the study (T1)	1.19±1.96*	0.95±1.69*	-0.72±1.61*	0.49±1.01
Number of practices with a z-score <-1.64 at T0	24	41	51	NA
Number of practices with a z-score <-1.64 at T1	3†	4†	21†	NA

* The mean difference between the z-score before (T0) and after (T1) the intervention is significant at the 0.001 level using a paired t-test.

† The difference between the number of practices with z<-1.64 before the start of the intervention and after the end of the intervention is significant at the 0.001 level, using a McNemar test for paired samples.

NA = Not Applicable

Table 2. Descriptive data aggregated at practice level for all practices and divided according to the quintiles of the aggregated z-score at baseline (Z_AT0)

	All	Q1	Q2	Q3	Q4	Q5
N	100	20	20	20	20	20
Mean z-score	-1.21±0.97	-2.60±0.53	-1.64±0.12	-1.22±0.16	-0.69±0.15	0.13±0.38
Range of z-score	-3.59 ; 0.83	-3.59 ;-1.87	-1.84 ;-1.49	-1.45 ;-0.94	-0.89 ;-0.38	-0.33 ;0.83
Mean CHD risk ± SD (%)	22.0±4.8	25.9±3.7	23.1±4.4	21.7±3.8*	20.4±4.9*	18.6±4.2†
Mean age±SD (years)	67±4	69±3	66±4	67±4	67±5	65±4
Mean diabetes duration±SD (years)	8±2	8±2	9±2	9±3	7±2	8±2
Female patients (%)	48	49	42	50	53	47
Mean HbA1c±SD (%)	7.2±0.5	7.4±0.3	7.5±0.7	7.2±0.4	7.1±0.3*	6.8±0.2†
Mean LDL-C±SD (mg/dl)	109±9	116±9	110±7	108±8*	108±7*	100±9†
Mean SBP±SD (mm Hg)	136±5	140±4	139±5	137±4	134±5†	132±5†

* The mean difference compared to Q1 is statistically significant at the 0.05 level using One-way Anova with Bonferroni post-hoc tests.

† The mean difference compared to Q1 is statistically significant at the 0.01 level using One-way Anova with Bonferroni post-hoc tests.

SD= Standard deviation

Table 3: Descriptive data aggregated at practice level and divided according to the COV of the z-score (-1.22) and according to the cut-off point for the CHD risk (25%).

	PRS (Group A+B)	Group A	Group B	No PRS (Group C +D)	Group C	Group D
N	50	22	28	50	5	45
Mean z-score	-1.97±0.63	-2.16±0.67	-1.81±0.57	-0.44±0.55	-0.69±0.30	-0.42±0.57
Mean CHD risk ± SD (%)	24.4±4.0	27.8±2.3	21.7±2.8†	19.4±4.3	27.4±2.4	18.6±3.6†
Mean age ± SD (years)	67±4	69±3	66±4*	66±4	71±4	65±4†
Mean diabetes duration ± SD (years)	8±2	9±3*	7±2	7±2	9±3	7±3*
Female patients (%)	46%	48%	44%	51%	39%	52%
Mean HbA1c ± SD (%)	7,4±0,5	7.5±0.6	7.3±0.4	7,0±0,4	7.1±0.3	7.0±0.3†
Mean LDL-C ± SD (mg/dl)	112±8	116±7	109±8*	105±9	108±7	105±9†
Mean SBP ± SD (mm Hg)	139±4	140±5	139±4	134±5	135±5	133±5†
% (N) of practices with zG < -1.64	40% (20)	41% (9)	39% (11)	8% (4)	20% (1)	7% (3)
% (N) of practices with ZC < -1.64	56% (28)	68% (15)	46% (13)	26% (13)	20% (1)	27% (12)
% (N) of practices with zB < -1.64	82% (41)	82% (18)	82% (23)	20% (10)	20% (1)	20% (9)
% (N) of practices with at least one parameter score < -1.64	98% (49)	100% (22)	96% (27)	56% (28)	60% (3)	56% (25)

Legend:

Group A= Practices Requiring Support at 'higher risk' ($z_A \leq -1.22$ AND CHD risk ≥ 25%(

Group B: Practices Requiring Support at 'lower risk' ($z_A \leq -1.22$) AND CHD risk <25%)

Group C: Practices not requiring support at 'higher risk' ($z_A > -1.22$ AND CHD risk ≥ 25%)

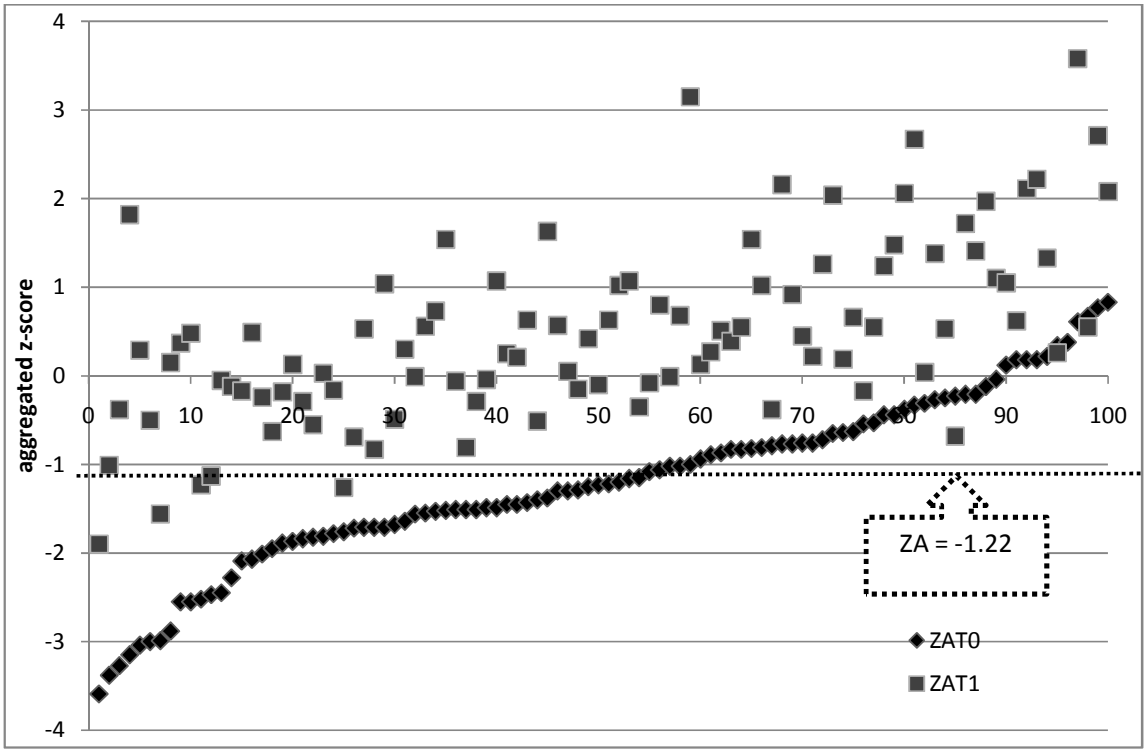
Group D :Practices not requiring support at 'lower risk' ($z_A > -1.22$ AND CHD RISK < 25%)

N = Number

* The mean difference compared to Group A is statistically significant at the 0.05 level, using One-way Anova with Bonferroni post-hoc tests.

† The mean difference compared to Group A is statistically significant at the 0.01 level, using One-way Anova with Bonferroni post-hoc tests.

Figure 1: Z-score of each practice at baseline (T0) and at the end of the study (T1). Each block represents the z-score of one practice, ♦ before the start of the intervention (T0) and ■ after the intervention (T1). Each practice is therefore represented by two blocks.



Chapter 6: Discussion

“He that will not apply new remedies must expect new evils; for time is the greatest innovator.”

Francis Bacon (1561-1626)

The 'care-trajectory' Type 2 Diabetes Mellitus

In September 2009, the "care-trajectory" Type 2 Diabetes Mellitus has been initiated as a new initiative for chronic care delivery in the Belgian health care system. A care-trajectory is based on the cooperation between 3 contracting partners: the patient, the General Practitioner (GP) and the specialist (endocrinologist). The individual care-trajectory gets started when all 3 parties have signed the contract of the care-trajectory that signs the involvement in optimal chronic care, and lines up the 3 partners in working to individually set targets. The general aim of a care-trajectory is to improve the cooperation between the GP and the specialist in the treatment of chronic diseases in order to optimize the patients' treatment. The patients will also be actively involved in the treatment of their disease. The criterion to start up with a care-trajectory is a clinical one: all Type 2 Diabetes patients who are treated or who should be treated by 1 or 2 daily insulin injections or incretin mimetic drugs are candidates for a care-trajectory. Patients who should be treated by insulin or incretin mimetic drugs are those who are uncontrolled (HbA1c target not reached) despite maximal oral treatment. The number of patients who are candidate for a care-trajectory in Belgium is estimated at 72.500.

The GP is considered as the 'central coordinator of the care-trajectory. The GP, together with the patient elaborates a treatment plan for the patient's management of Type 2 Diabetes including quantified individual goals (targets) for the control of glucose (HbA1c), blood pressure, blood lipids and a few other parameters. This plan also needs the approval of the endocrinologist and the 2 involved physicians are encouraged to confer on the plan, and on the specific treatment plan for insulin. Afterwards, the patient is sent to the educator who will teach the patient specific guidelines on the personal management of insulin injections and glucose monitoring. The GP will also be asked to deliver some data: BMI, HbA1c, LDL-C, systolic and diastolic blood pressure. Data will be extracted out of the electronic medical file and will serve to evaluate the quality of care.

The endocrinologist is responsible for the necessary continuing medical education of the GPs in the region where they work. The individual specialist should also be available for individual coaching of the GP by means of the modern communication channels (email, telephone, web-based...).

A necessary paradigm shift.

The care-trajectories can be considered as the Belgian adaptation of the Chronic Care Model. In 2007, the KCE (Belgian Health Care Knowledge Centrum) published a report that urged to implement this model in the Belgian Health Care system (1). Belgian GPs just like in several neighbouring countries, have a tradition to work in a **'Retro-Active'** demand oriented way. This means that GPs come to action when patients ask to help them with their complaints and symptoms. The treatment process mainly occurs between the individual practitioner and the individual patient during the consultation. This is called the **"Colloque Singulier"**. Many GPs feel responsible as a doctor in the frame of this individual care process, but not beyond. The GP sometimes refers to a specialist, but in our country, there is no tradition of teamwork cooperation between GPs and specialists. Indeed, in a lot of cases, the treatment is relatively simple and is within the competency scope of the broad trained GP. The treatment can be based on existing directives, but busy GPs often rely on their experience to administer the right treatment to their patients. As such, many doctors still consider that they have a **"Therapeutic freedom"** to treat the patients according to their own medical judgment. This way of working is deeply anchored in the Belgian general practice, but is also strongly present in specialist care. It has well functioned for over 60 years in a system that was both mentally and organizationally oriented to cure acute diseases, especially infectious diseases.

The clinical epidemiology however is changing. The ageing population, the changed life style habits and the better survival rates of patients after acute disease events (e.g. a heart attack) are associated with an increased prevalence of chronic diseases, such as Type 2 Diabetes. These diseases slowly evolve towards serious complications. For the moment most doctors treat chronic diseases in the same way as they treat acute diseases. Nearly the entire process of care for patients takes place during the consultation or home visit.

This approach is considered as a barrier to quality diabetes care. When a patient with diabetes spontaneously consults a GP, he or she often consults because of other reasons than his or her diabetes. Diabetes is treated in the second or third place during the consultation. Patients and GPs often only have a few minutes to spend to diabetes, far too little time to evaluate essential objectives of the disease. In a lot of cases, there is no organized plan to follow-up the treatment and to screen for early signs of complications. The time for detailed discussions on life style is lacking

and teamwork with a dietician or educator is often absent in primary care. Moreover, there is no tradition to work with patient registries. As such, patients who do not consult spontaneously can get lost for years until complications occur.

Chronic diseases are supposed to require a totally different approach than acute diseases (2-4). The Chronic Care Model represents a structured and scheduled follow-up of chronic diseases. In this model, health professionals and patients anticipate eventual problems and complications **("pro-active approach")**. This requires a mentality change with the physicians and a change in organizational approach. Good diabetes care is considered to require planning and preparation. In this model, GP practices should have a registry of all their diabetic patients. This registry can be used and checked beyond the individual GP-patient consultation, e.g. to enable a call/recall system. In the Chronic Care Model, a great deal of the attention is spent on informing and motivating patients (**patient empowerment**). Moreover, in chronic care, there is a need for a **multidisciplinary approach, shared care**. In this system, each professional is aware of his own tasks and responsibilities. The professionals share information and knowledge and work together as a team in mutual agreements, according to a specific protocol that is based on scientific guidelines (**'evidence -based medicine '**). In this system, several tools are used to evaluate and to optimize the care for patients, such as patient registries, feedback systems, specific CME, coaching...

Care-trajectories and the Leuven Diabetes Project

The care-trajectories want to encourage General Practitioners and specialists to adopt new paradigms and working styles in the routine care for patients with chronic diseases. The National Institute for Health and Disability Insurance (NIHDI) has chosen two pathologies to start with: Chronic Kidney Disease and Type 2 Diabetes. In the case of Type 2 Diabetes, a subgroup of patients has been chosen, those who are out of control on oral treatment and need insulin treatment and thus who are more in need of a multi-disciplinary approach. This approach could be criticized because the NIHDI chose to take in charge end stage patients, whereas most benefit could be drawn when newly diagnosed patients are maintained in good control. However, uncontrolled patients are difficult to treat and GPs mostly feel the urgency to consider shared care in this category of patients. As such, this subgroup

of patients can be considered as a leverage to change GPs mentality and to introduce the new working paradigms. Moreover, the NIHDI-report on care-trajectories explicitly mentions the option to extend the care-trajectories to all patients with Type 2 Diabetes.

The support measures in the care-trajectory (CME, benchmarking feedback, coaching of GPs and diabetes educators, patient education) are very similar to the interventions that were elaborated in the Usual Quality Improvement Program (UQIP) of the Leuven Diabetes Project. Indeed, the Leuven Diabetes Project and its sister project the "Diabetes Project Aalst" were set up as pilot projects to prepare a nation-wide implementation of a disease management program. The scientific conclusions of these projects can be used to guide the further implementation of the care-trajectories.

Therefore, we will critically evaluate the findings of this project in the light of the national implementation of the care trajectories. In this discussion, we will evaluate the results of the Leuven Diabetes Project with regards to the research questions that were described in the introduction of this thesis. The main objective of this PhD project was to assess the quality of care for patients with Type 2 Diabetes and to evaluate the effectiveness of quality improvement measures in the Belgian health care setting.

Room for improvement

We first answered the question *"Is there room for improvement in the care for Type 2 diabetic patients in Belgium*?" in a cross sectional study conducted in a region of 357,000 inhabitants that surrounds the medical university hospital of Leuven. The aim of this study was to picture the profile of patients with Type 2 Diabetes in Belgium and to study the quality of care in the primary care setting. Quality of care was evaluated by the achievement of three major treatment targets: HbA1c <7%; Systolic Blood Pressure ≤130 mmHg; LDL-Cholesterol <100mg/dl. The HbA1c target was reached in 54% of the patients, the Systolic Blood Pressure target in 50% of the patients and the LDL-C target in 42% of the patients. Statin use was present in only 39% of the patients. Patients treated by insulin therapy and with follow-up in diabetes centres obtained significant lower values for HbA1c (7.5±1.2% vs. 7.8±1.5%, p=0.038) and for LDL-C (90±34 vs. 111±37, p<0.001) compared to insulin-treated patients only followed up in primary care. We obtained some indications that clinical

inertia was present in the critical transition from oral anti-diabetic treatment to insulin treatment. Our results suggest that quality of Type 2 Diabetes care can be improved in those patients primarily treated by the GPs. Patients, exposed to shared care between GPs and specialized care obtain better results in glycemia, blood pressure, lipid and pharmacological treatment targets. Moreover, the data presented in this manuscript could even be more favourable compared to data of the overall population because of possible biases in the study. Taking into account this consideration, we have good arguments to state that indeed it is necessary to try to improve diabetes care in Belgium in the primary care setting. The results of this study also argue for a better integration of the different care levels and the introduction in the GP setting of the more structured, consensus and guideline-based approach characteristic to the diabetes clinics.

The results of a quality improvement trial

"Is it possible to improve the quality of diabetes care?" To answer this question, *w*e conducted a *"Quality Improvement Effectiveness Study"* implementing a two-arm Quality Improvement Program (QIP). The precise research question of the trial was whether improved patient outcomes could be achieved with a basic support program for GPs and patients (Usual QIP), and whether intensified support of GPs and patients in the advanced (Advanced QIP) arm which paid special attention to shared care, patient compliance and adherence to lifestyle changes would further improve outcomes in T2DM patients achieved by the UQIP. In cluster randomized trial with mean follow-up of 18 months, UQIP (53 GPs, 918 patients) merged standard interventions including evidence-based treatment protocol, annual benchmarking, postgraduate education, case-coaching for GPs and patient education. AQIP (67 GPs, 1577 patients) introduced additional interventions focusing on intensified follow-up, shared care and patient behavioural changes. The results showed that in UQIP, endpoints improved significantly after the intervention: HbA1c -0.4%, CI95%[-0.4;-0.3]; SBP -3 mmHg, CI95%[-4; -1]; LDL-C -13 mg/dl, CI95%[-15; -11]. In AQIP however, there were no significant better improvements in outcomes. The overall proportion of patients reaching the HbA1c, SBP and LDL-C target respectively increased with 13% 8% and18%. After the intervention, 53% of the patients were on statin therapy (+14%).

As a conclusion it was made clear that a multifaceted program, including different interventions used to support General Practice in its care for diabetes Type 2 patients was associated with important improvement over time of the major diabetes related cardiovascular risk factors. Intensified follow-up with interventions that focused on more intensified shared care and more intensified training on patient behaviour changes did not yield additional benefit.

Methodological issues

Yet, in the absence of a randomized control group, there is no hard, univocal evidence that the UQIP really "caused" better outcomes. During the preparation period, we decided we would not assign a 'real' control group because we deemed it impossible to conduct a randomized controlled trial (RCT) without biasing the control group. The RCT is the 'archetype' of clinical research design. This design is the only one that allows for causal interpretation of the study results because in an RCT, all possible confounders with potential bias on the results should equally be divided in the two randomized arms. However, the conventional parallel group randomized trial presents some limitations regarding population-based health interventions (5;14). Randomization - even at the cluster level - might not remove all origins of bias, even if it eliminates all observable differences between groups (15). Designing a correct control group can be problematic in population based interventions. All studies need data. In our case these data had to be delivered by the GPs who were also the subject of the study. The GPs need to be motivated and reminded to deliver data. Yet, reminding the GPs to deliver data and the process of delivering data (especially when they write it down on paper) is a powerful intervention that raises the awareness of the physician on his/her own quality of care. All these actions can be considered as interventions with an effect (potential bias) on the control group. So, we were aware that we could not assign a <u>real</u> control group, i.e. a group of GPs who did not receive any stimulation to change behaviour. A second problem is the problem of contamination. Randomization of practices in one region gives the problem that neighbouring practices adhering to the same quality circles, working in the same region and appealing on the same services are divided in either a control group or an intervention group. Yet, in reality it is possible that practices of the 'control group' make appeal on interventions dedicated to the intervention groups. Finally, lack of blinding of the randomized arms can stimulate the 'control group' to

perform as well as the intervention group or could eventually cause the opposite effect. In the case of UQIP, several GPs affirmed to be extra motivated to deliver good quality of care. This lack of blinding probably resulted in the bias that the most motivated GPs in the UQIP-arm completed the trial while the less motivated dropped out at the beginning of the trial.

If QI researchers want to use a real control group in a RCT design, then they should pay special attention to avoid these matters of bias. A potential solution is the complete blinding of the randomized control group, i.e. that the control group ignores taking part to a study. Therefore, privacy rules should be changed and data should automatically be extracted from the electronic medical file. Contamination could be avoided by randomizing quality circles or communities rather than practices. An alternative is the “Latin square” or “incomplete block design”. In this design, both arms receive a different intervention, e.g. one arm receives an intervention to improve the care for asthma, the other for diabetes. Each arm serves as a control group for the other group. In our study, it was not possible to design a balanced block design because the trial was widely announced as a trial to improve diabetes care, long before the start of the field phase. Thus it was not possible to blind the GPs in a balanced block design. Moreover, in such a design both groups still know that they are part of an experimental trial and still have to deliver data for both diseases. As such, awareness about the quality of care for the ‘opposite’ disease can still occur in the ‘control group’. This is what happened in the MIKSTRA-study in Finland. Three groups received each an intervention to improve adherence on two guidelines. Yet, some health care centres preferred to work on adherence to other guidelines than those they were supposed to work on. This study neither did show any difference in quality improvement between the three groups (6). The “delayed intervention” RCT / stepped wedge design are other alternatives. In these designs both randomized arms receive an intervention, but in one arm, the intervention is postponed. In such a design, the pre-intervention data of the delayed intervention group serve as control data for the post-intervention data of the immediate intervention group. Other possibilities are the preference trials, randomized consent designs and the N of 1 design (14).

When it is actually not possible to assign a real control group within the RCT-design, then an alternative or a hybrid design (with an external control group) should

be taken in consideration. In all cases, there should be a written consensus in the form of a trial protocol about the design before the start of the field phase. This consensus was not complete in the case of our trial. We reached consensus about the necessity to have two randomized arms, but we underestimated the problems related to the absence of a randomized control group. Moreover, we could not reach consensus on the means how to include an external control group. Finally, we decided to compare the change of the primary outcomes between a random sample of the intervention population and a 'reference group', a matched subgroup of patients with T2DM from the «INTEGO» Registry Network.

The value of insurance claims data

In June 2006 we also obtained the approval and the necessary budget to construct a controlled design, based on insurance claims data combined with laboratory data from people in the intervention region. We used the opportunity to start the data collection three years before the intervention. So, we evaluated the five year (2002-2007) evolution of outcome and process parameters in the care for Type 2 Diabetes patients taking glucose lowering medication and living in the region of Leuven. The measured outcomes were HbA1, LDL-C, Triglycerides and related process parameters. Additionally, we have evaluated whether the evolution of those parameters in patients clustered around GPs' who participated to the Leuven Diabetes Project from 2005 till the end of 2006 was significantly different from the evolution of parameters of patients clustered around GPs who did not participate. This study was not only important with regards to the results. The entire set-up of this study was important because it was the first time in Belgium that consumer data routinely registered by health insurance companies were combined with laboratory data in order to evaluate the evolution of quality of care. As such it was a pilot project to study the feasibility of such exercises. The study showed that claims data can effectively be used to evaluate the long-time evolution of some essential diabetes related outcomes. They allow for evaluating results of a large number of patients all over the country without the necessity to set up specific trials with a selected cohort. These results should however be interpreted with the necessary caution because of several sources of bias. Taking into account the limitations of this study, it is probably possible to state that a change in glucose treatment in patients with diabetes occurred in the region of Leuven in the period that the Leuven Diabetes Project was

starting up. It is also possible to state that cholesterol treatment was implemented in the region far before the start of the project, but the project may have boosted this implementation, especially by GPs who participated to the project.

Evidence on the effectiveness of the Quality Improvement Program

In the absence of a control group, the design of the randomized trial did not allow to draw a formal causal relationship between the Quality Improvement Program (UQIP) and the improved patient outcomes. However, the overall results of the randomized trial and the results of the study based on the insurance claims data provided good arguments that strengthen the evidence of effectiveness.

First, the improvement over time of Hba1c, LDL-C and SBP in the UQIP-arm of the randomized trial lies in the same range or is even better than the improvement over time of the intervention group of other, similar intervention studies. Some of these intervention groups showed significant differences with the respective control group. Secondly, higher baseline values were significantly associated with better improvement of HbA1c, SBP and LDL-C. The intensification of blood pressure treatment and the initiation of statin and insulin treatment were both in AQIP and UQIP significantly higher in patients who were not in good control at baseline. Thirdly, compared to a matched group issued from the national (Flemish) INTEGO registry network, the positive evolution of HbA1c and LDL-C in the UQIP-arm was significantly better. This registry based network of GPs is used as a trend watcher, clearly spread all over the Flemish region. It collects also HbA1c and LDL-C. These are laboratory data that are automatically incorporated in the Electronic Medical Record and thus can be considered as reasonably reliable.

The analysis of the insurance claims data strengthened the evidence. In this study, we looked for differences in the evolution of outcome and process parameters in patients clustered around participating GPs versus patients clustered around non-participating GP's. When comparing the primary outcome parameters in those 2 groups, we could only observe a significant difference in the evolution of LDL-C. The real important differences were noticed in the process parameters, like the proportion of patients receiving an annual eye examination and a micro-albuminuria screening test. These process parameters are considered as important because early detection and treatment of diabetes symptoms and complications may reduce morbidity and

mortality (16; 17). Moreover, we also observed a significant difference in 2005 and in 2006 in the proportion of patients taking statin treatment. This difference can explain the difference in LDL-C evolution. Finally, there was a significant difference in insulin treatment in 2006 between 'participants' and 'non participants'. This difference has probably occurred too late so that we did not observe significant differences in the HbA1c evolution.

The annual investment costs of UQIP amounted to €164 per patient (vs. AQIP €207/patient/year), a rather modest amount compared to the total annual diabetes-related medical costs estimated at €1207 (12). A cost-effectiveness analysis alongside the insurance claims data analysis showed an acceptable cost-effectiveness-ratio of the program with – in the worst case scenario – a calculated amount of 10398€ per saved quality adjusted life-year (7).

Care coordination: toward new partnerships in health care

In a qualitative study, nested in the controlled trial, we tried to get more insight how a Quality Improvement Program interacted with the existent individual and social patterns in health care. The primary finding was that the project accomplished more than merely improving the quality of care. All interviewees were unanimous that this project was beneficial because it added value to their jobs. Most of the GPs reported also a major improvement in their diabetes care and indicated that changes resulted from a conscious decision based on interconnected key elements during the quality improvement process: enhanced knowledge, improved motivation and awareness, and a greater sense of responsibility. Most GPs confirmed improved relationships and communication with specialists. They also perceived a change in attitude on the part of the endocrinologists toward them, which markedly enhanced the GPs' motivation and sense of responsibility. This is a very important finding since patients with chronic conditions mostly interact with more than one provider. Treatment of complex conditions often requires consultation with multiple specialists. Logically, high quality chronic care demands concerted action, collaboration and coordination of care. The Leuven Diabetes Project has shown that general practitioners and specialists can collaborate in partnerships and team spirit instead of competing with each other. In the international literature, 'teams' are often understood as either hospital-based (an endocrinologist in a hospital, with paramedics) or primary care based. We expanded the contents of this term in our project to a partnership above

all layers of care. In our opinion, this is a prerequisite to high quality chronic care: we need to focus on the full population and not on what either primary care or hospitals should do.

The project also strengthened some views on the development of good partnerships:

- If one provider should be considered as the main responsible of care delivery, for most patients with a chronic condition, the GP is the appropriate professional to play this role.
- However, the GP should rely on partners in healthcare and consider his role as part of a real teamwork. Therefore, there should be a written and consensus based protocol that is supported by all partners in healthcare. This protocol should describe the rights, responsibilities and tasks of all involved professional disciplines. It should not only develop a stratified task division regarding the individual patient follow-up. It should also develop a framework regarding the follow-up of groups of patients and matters of coaching and medical education.
- In this teamwork, specialists do not only have the task to directly treat the most difficult and complex patients, but they also have to form and coach the GPs enabling them to fully play their role as central coordinator.
- In order to stimulate partnerships and team spirit, the communication, the interaction and the personal contact between the professionals should be guided by a health care 'coordinator' or 'manager' with special attention to eventual relational problems. This local process coach, called the "promoter" or "manager", was considered indispensable by the participating GPs.

Changing a complex system: need for well-designed implementation strategies

Our qualitative research also highlighted the complexity of quality improvement. Over the last years, the health care system has increasingly been considered as a Complex Adaptive System, a view that is opposed to the mechanistic view considering the health care system as a predictable 'machine' (8). The theory has been adopted in the landmark report of the Institute of Medicine "Closing the Quality Chasm" (9) but its implications on quality improvement and quality improvement research have yet to be explored (10). According to this theory, patients, general practitioners and other involved providers can be considered as

'agents', individual elements with freedom to act in ways that are not always totally predictable. All 'agents' compose a system with several subsystems. Agents and subsystems interact with each other. As such, a system is an integral whole in which things are interdependent, rather than a mixture of things isolated from each other. Moreover, the whole system and all its components are in a constant state of movement and change. In such a system, changes emerge from the interaction between agents and subsystems. The effect of whatever intervention in such a system is not determined in a linear, predictive, 'mechanistic' way. Each intervention induces reactions within the system and the final outcome partially depends on the nature, intensity and interaction of the internal 'forces' that are present in that system.

Our health care system, that behaves as a Complex Adaptive System is increasingly being challenged by the 'epidemic' of chronic diseases. As a consequence, the system must be revised in its structure and financing, in the care delivery to patients, in the organization of practices and hospitals and in the organization between practices, hospitals and regions. In relation to chronic care delivery, this change will demand a change in mentality of the health care providers who will have to adopt new concepts such as team spirit and partnership, organized care of groups of patients, pro-active planning of the care and protocol-based practice with quality evaluation. In our opinion it is not possible that such important changes can pass in a spontaneous way. Changing the system and the mentalities from an acute care delivery system into a system that is also fitted for chronic care delivery demands active implementation strategies brought together in a well designed plan. This plan must be tailored to the national and local context and must be preceded by a detailed "diagnostic analysis" of the local context (13;14). A rigorous "diagnostic analysis" of the setting is of utmost importance for all those who want to change the field situation. This analysis should not only evaluate the barriers to high quality care, but should also picture the target group of the intervention and the potential strengths of the particular setting. As a consequence, the implementation interventions should be tailored to the particular setting and target group. Indeed, some theoretical important interventions may not be applicable because of insurmountable barriers. On the other hand, the specific setting can also induce some facilities that are not available elsewhere. As such, every setting is characterized by both barriers and facilitating

factors to successful guideline implementation. These factors should be carefully analyzed, using several complementary methods.

Future directions in quality improvement

Should our health care system change the basics of the financial allocation routines? This PhD-project does not deal with changing the financial allocation systems and reimbursement methods. Yet the current fee-for-service payment system has increasingly been criticized (11). Fee-for-service is unlikely to promote quality improvement and tends to reward excessive use of services, high-cost and complex procedures. Care coordination and other global services which contribute to high-quality care but that rely less on technical resources tend to be undervalued. Providers often miss occasions for collaboration since the payment system rewards neither team management nor the integration of services across care settings.

The introduction of pay-for-performance systems or elements of it certainly could stimulate a quality culture and teamwork in our health care system. Care trajectories on chronic conditions, like the program we evaluated, could be considered, planned and implemented as a Pay for Quality program.

It should however be noticed that P4P is no magic bullet. Until now research did not find one 'magic bullet' intervention or program that spectacularly improved the quality of care. On the other hand, the insurance claims data analysis showed that some outcome parameters have progressively improved in the whole region of Leuven since 2002, thus before the introduction of well organized Quality Improvement Programs. Other, international studies have shown a similar evolution (18). This improvement might be due to an increased attention for diabetes care with publication of landmark studies and guidelines, the combination of different national, local or regional quality improvement initiatives and the introduction of new, more powerful drugs. Quality improvement as a continuity process probably needs multiple initiatives and sustainment.

Our study also confirmed that in the usual care, as measured at the beginning of our study, about half of the patients already do reach the target. For those patients, a clinical significant improvement over time is not possible. Therefore, it may be reasonable to concentrate the resources and efforts of Quality Improvement Interventions on those practices and patient populations that are out of control. For

this purpose, we constructed a composite Z-score that is weighted based on the number of patients per practice. This scoring system evaluates whether the mean practice values of parameters that are of vital importance are significantly different from a preset target. This indicator can be used in a nation-wide monitoring system of general practices to highlight practice populations at mortality or morbidity risk due to modifiable risk factors. Those practice populations may be in need of extra support to decrease this risk. Moreover, the ability of this indicator to detect change makes it an important metric to evaluate the efficacy of a Quality Improvement Program.

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Chapter 7: Conclusions

The Leuven Diabetes Project, serving as a pilot project for the nation-wide introduction and implementation of a Chronic Care Model has provided substantial evidence for the need of a comprehensive plan. This plan should combine a reinforcement of the structure and organization in primary care with improved coordination of care between General Practitioners and Specialists, increased evidence-based guidance of General Practitioners and patient education by a nurse educator as a new collaborator in the primary care setting.

The LDP showed that such a plan is associated with an improvement in the quality of diabetes care, both in terms of essential outcome and process indicators that are related to protocol based working and to early awareness for complications.

A basic program was associated with significant improvement over time. Enhancing the frequency or intensity of the interventions of the program and/or adding supplementary interventions to a basic program do not necessarily induce better improvement of the patient outcomes.

The program also showed other benefits. The LDP program has led to a better understanding and better relationships between the different health care professionals and to more satisfaction and more work pleasure as appreciated by the General Practitioners. The positive perception of the program as a support initiative is a precondition for success.

Diabetes care in the Belgian primary care setting

- General practice can be considered as the pivotal level in the care of people with Type 2 Diabetes since GPs take care for the majority of Type 2 Diabetes patients.
- 'Spontaneous' implementation of certain diabetes recommendations, notably with regards to cholesterol treatment, has been observed several years before the start of whatever Quality Improvement Program.
- Nevertheless, room for improvement exists.
  - About half of the primary outcome targets are reached in usual primary care.
  - Clinical inertia, especially regarding insulin therapy onset is present.
  - Patient lifestyle habits and motivation to comply with the complex diabetes treatment are a matter of concern.
- Variability between patients and between practices is rather high

- **Effective measures to improve the quality of diabetes care in the Belgian health care system**
  - A comprehensive program that
    - reinforces the structure and organization in primary care through the introduction of a management function
    - introduces a better coordination of and task division between specialist and generalist care
    - provides a more guideline-based approach in general practice
    - introduces patient education by a nurse educator in the primary care setting

    is associated with significant improvement in the quality of care:

    - Improved clinical outcomes of diabetes patients
    - Improved follow-up (e.g. screening on complications)
    - Improved prescription of 'guardian drugs' (e.g. statins) and increased prescription of insulin therapy
    - Improved communication and relationships between specialists and generalists

        - Improved job satisfaction as experienced by the General Practitioners

    - This program was composed of following basic interventions: diffusion of a treatment protocol, tailored CME for GPs, benchmarking feedback, task description of the involved professionals, case coaching by a specialist, organization of a multidisciplinary diabetes team in primary care and possibility to refer patients for patient education.
    - These measures are essentially 'generic' measures that are transposable, i.e. they could eventually be introduced to better manage other chronic conditions.
    - Additional interventions in the AQIP-arm involving three areas - a more intense, three monthly follow-up of GPs, actively stimulated shared care with an interdisciplinary diabetes care team care and additional facilitation of patient behaviour changes - did not add substantial benefit.

- **Issues about future nation-wide implementation**
    - The improvement over time at the end of the intervention was clinically significant in patients that were at baseline out of control and not in patients who were already on target before the start of the project. Therefore, it could be reasonable to focus or to limit nation-wide Quality Improvement Programs to specific target groups: newly diagnosed patients, patients and patient populations who are out of control as well as practices with a lot of uncontrolled patients.
    - It is recommended to organize a system for monitoring practices in relation to the relevant diabetes outcomes. A composite z-score could be a useful tool for nation-wide monitoring of general practices.

- **Conclusions about Quality Improvement and Implementation Programs**
    - Quality improvement cannot be considered as a linear predictive process. Up to now, there is no 'magic bullet' that spectacularly improves quality of diabetes care.

- Successful implementation of Quality Improvement Programs should always be preceded by a 'diagnostic' analysis of the setting, including the barriers and the facilitators to change.
- Successful implementation should target all important, removable barriers at all levels in a system and not reduce to one single level.
- Implementation programs must be well planned, structured and organized, based on different available theories on change management and behaviour change.
- Quality improvement is not only a 'rational', 'technical' matter. The preponderant importance of positive motivational attitudes has clearly been shown. Therefore, implementation programs should take into account the motivational and perceptive reaction of the target audience and should be considered as "campaigns to win the hearts of the target audience".
- Quality improvement programs should spend attention to the quality of the relationships between the different involved partners since this element has been described as essentially for the participants' motivation.

Executive summary

As explained in the **introduction** of this PhD-thesis, the prevalence of Type 2 Diabetes has dramatically been growing for about 20 years. The disease has recently been labelled as the first world-wide non infectious epidemic (UN December 2006). Suboptimal treated Type 2 Diabetes Mellitus provokes major long-term complications with essentially a vascular origin, either micro-vascular (kidney failure, neuropathy, retinopathy) or macro-vascular (heart attack, stroke, peripheral arterial disease).

Clinical evidence suggests that aggressive, timely, and multi-factorial interventions aimed at controlling risk factors such as high blood pressure, blood lipids and glycemia can reduce diabetes related complications. Treatment should aim at changes in lifestyle habits and daily use of multiple drugs, once Type 2 Diabetes has been diagnosed. Treatment should be long-term and target-driven with intensified interventions aimed at all validated targets. Lifestyle approach (stop smoking, regular physical exercise, healthy diet and weight loss in case of obesity) is of primary importance. Important biomedical targets are the reduction of HbA1C (target 7%), blood pressure (target 130/80 mm Hg), blood lipids (LDL-cholesterol < 100 mg/dl).

However, international studies have shown a gap between the optimal recommended treatment of Type 2 Diabetes and the actual treatment. Therefore, we examined in this PhD project the Belgian situation. More concretely, we evaluated whether it is necessary and possible to improve the quality of Type 2 Diabetes primary care in Belgium at the outcome level.

In the first chapter we answer the question *"What is the quality of care as measured by patients' cardiovascular intermediate outcomes in a Belgian health care setting?"* The chapter relates to a cross-sectional study conducted in 2495 diabetes patients living in a region of 357,000 inhabitants that surrounds the medical university hospital of Leuven. Overall metabolic control was found to be comparable with the results of studies in primary care settings in other countries. Nevertheless there is ample room for improvement since the HbA1c target was reached in 54% of the patients, the Systolic Blood Pressure target in 50% of the patients and the LDL-C target in 42% of the patients. Patients, exposed to shared care between GPs and specialist care obtained better results in glycemia, LDL-C and pharmacological treatment targets (aspirin and statin prescription). Finally, indications on clinical

inertia were shown, especially concerning insulin treatment onset. These results suggest that also in Belgium quality of Type 2 Diabetes care could be improved in those patients primarily treated by the GPs.

The second chapter deals a ***"Quality Improvement Effectiveness Study"*** and examined the effectiveness of a two-arm Quality Improvement Program (QIP) that mainly focused on supporting General Practitioners in the care for patients with T2DM. Improvement from a basic support program for GPs and patients (Usual-QIP) was compared to the results from an intensified support program for GPs and patients (Advanced-QIP). The Usual-QIP (53 GPs, 918 patients) included the availability of a clear evidence-based treatment protocol, annual benchmarking, postgraduate education and individual case-coaching if judged necessary by the GP. GPs had the availability to refer patients for patient education and follow-up to a Diabetes Support Team. Advanced-QIP (67 GPs, 1577 patients) added an intensified follow-up, active stimulation to shared care and supplementary training on patient behavioural changes. Endpoints improved significantly over time both in UQIP and AQIP. No significantly better outcomes could be proved in AQIP as compared to UQIP. The overall proportion of patients reaching the HbA1C, SBP and LDL-C target respectively increased with 13%, 8% and 18%.

This improvement over time of HbA1C, Cholesterol and Systolic Blood Pressure values in the Leuven Diabetes Project was comparable to the results of other similar studies with comparable baseline values. However, in the absence of a randomized control group (a group of GPs and patients without any support intervention), there is no hard, univocal evidence that the UQIP really "caused" better outcomes. Therefore, we searched for additional arguments that can strengthen the evidence about the effectiveness of the program.

In chapter three we describe the evaluation of the five year (1/12002-1/1/2007) evolution of outcome and process parameters in the care for (probable) Type 2 Diabetes patients taking glucose lowering medication and living in the region of Leuven. Therefore, a new database was created, It combined consumer data that are routinely collected by health insurance companies and laboratory data. In order to respect the privacy rules, a complex methodology with double coding of all data had to be used. The primary objective of this study was to describe the 5-year evolution (2002-2007) in the care for persons treated by glucose lowering medication in a region that was the setting of a Quality Improvement Program (Leuven - LDP) for the

last two years of this period. Additionally, we have evaluated whether the evolution of those parameters in patients clustered around the GPs who had participated to the LDP was significantly different from the evolution of parameters of patients clustered around GPs who had not participated. This study was not only important with regards to the results. The entire set-up of this study was important because it was the first time in Belgium that consumer data routinely registered by health insurance companies were combined with laboratory data in order to evaluate the evolution of quality of care. As such it was a pilot project to study the feasibility of such exercises. The results of this study show that studies based on insurance claims data can be useful to evaluate the long-time evolution of some essential diabetes related outcomes. Yet those results should be interpreted with the necessary caution because of several sources of bias. Taking into account the limitations of this study, it is however possible to state that a positive change in glucose treatment in patients with diabetes occurred in the region of Leuven in the period that the Leuven Diabetes Project was starting up. It is also possible to state that cholesterol treatment was implemented in the region far before the start of the project, but the project may have boosted this implementation, especially by GPs who participated to the project. Moreover, essential process parameters like screening on eye and kidney complications improved significantly after the start of the intervention program (2005) in patients clustered around participating GPs but not in patients clustered around GPs who did not participate to the LDP.

Chapter four deals with an analysis of the barriers and facilitators to high-quality diabetes care as experienced by GPs who participated in the Quality Improvement Program. In a qualitative study design, twenty out of the 120 participating GPs were interviewed. The Leuven Diabetes Project seems to have accomplished more than merely improving the quality of care outcomes. Most GPs confirmed improved relationships and communication with specialists. They also perceived a change in attitude on the part of the endocrinologists toward them, which markedly enhanced the GPs' motivation and sense of responsibility. This is a very important finding since patients with chronic conditions mostly interact with more than one provider. Treatment of complex conditions often requires consultation with multiple specialists. Logically, high quality chronic care demands collaboration and coordination of care. The Leuven Diabetes Project has shown that general practitioners and specialist can collaborate in partnerships and team spirit instead of

competing with each other. Precondition to this success is the perception of the program as a support program for the daily care by healthcare professionals and their patients.

This qualitative research also highlighted the complexity of quality improvement. The program influenced interpersonal relationships and evoked complex changes that go beyond individual physicians and patients. GPs were confronted with their limitations to change patients' lifestyle habits, and their own hesitations in changing their habits and beliefs. Several GPs mentioned scepticism about the added value of collaborative shared care, notably with the diabeteseducator, a newly introduced function in primary care. Implementing some necessary practice changes to better care for chronic conditions was another major problem.

Finally, the study supported the message that Quality Improvement Programs should pay special attention to systematic and individual relational- and communication issues, and should explicitly discuss rights, responsibilities and tasks between patients, GPs, nurse educators and specialists.

Chapter five reflects on some issues in relation to possible nation-wide implementation of a diabetes disease management program in general practices that show a large variety in populations, intervention styles, and disease outcomes. In this chapter, we propose a practice based monitoring tool. It is conceived as a composite Z-score that evaluates whether on the total practice population the mean practice values of HbA1c, LDL-C and Systolic Blood Pressure (SBP) are significantly higher than the commonly set targets for optimal diabetes care. We tested its validity, reliability and sensitivity to change on the group results of the practices that participated in the Leuven Diabetes Project. There was good correlation between the practice z-score and the average risk on CHD. Moreover, the results indicated that the z-score was able to discriminate between practices with populations at higher risk from practice populations at lower CHD risk. Most practices showed a considerable improvement in the z-score during the course of the intervention. This scoring system could be used in a nation-wide monitoring system of general practices to highlight those practice populations at increased cardiovascular risk due to modifiable risk factors. Those practice populations may be in need of extra support to decrease their cardiovascular risk. The ability of this indicator to detect change

makes it an important metric to evaluate the efficacy of Quality Improvement Programs.

General conclusion: The Leuven Diabetes Project serving as a pilot project for the nationwide introduction of a Chronic Care Model has provided substantial evidence that the implementation of a comprehensive plan that combines a reinforcement of the structure and organization in primary care with coordination of care between General Practitioners and specialists, increased evidence-based guidance of General Practitioners and patient education by a nurse educator in the primary care setting is associated with an improvement in the quality of diabetes care, both in terms of essential outcome and process indicators.

Enhancing the frequency or intensity of the interventions of the program and/or adding supplementary interventions to a basic program do not necessarily induce better improvement of the patient outcomes.

In addition to the outcome improvement, the program has led to a better understanding and better relationships between the different health care professionals and to more satisfaction and more work pleasure as appreciated by the General Practitioners. The positive perception of the program as a support initiative is a precondition for success.

Samenvatting: Doeltreffende Antwoorden op de Klinische Uitdagingen in de Chronische Zorg: Bevindingen van het Diabetes Project Leuven.

De laatste 20 jaar werd een dramatisch sterke stijging van de prevalentie van Diabetes Mellitus Type 2 waargenomen. De ziekte werd onlangs bestempeld als de eerste epidemie op wereldvlak van niet besmettelijke oorsprong (Verenigde Naties, december 2006). Suboptimaal behandelde Type 2 Diabetes Mellitus leidt op termijn tot ernstige, zelfs levensbedreigende verwikkelingen van microvasculaire oorsprong (nierfalen, neuropathie, retinopathie) of macrovasculaire oorsprong (hartaanval, Cerebro Vasculair Accident, perifeer arterieel vaatlijden). Vroegtijdige, agressieve en multifactoriële behandeling met als doel het controleren van de belangrijkste risicofactoren zoals hoge bloeddruk, verhoogde cholesterolwaarden en een verhoogde bloedsuikerspiegel (weergegeven door de parameter HbA1c) vermindert op een significante wijze het risico op verwikkelingen. De behandeling moet ingesteld worden zodra de diagnose gesteld wordt en moet zowel gericht zijn op het wijzigen van de levensgewoontes als op het dagelijks innemen van meerdere soorten medicatie. De behandeling dient levenslang gevolgd te worden en is gericht op het behalen van gevalideerde doelstellingen. Aanpassingen van de levensgewoontes zoals rookstop, regelmatige lichaamsbeweging, gezonde voeding en gewichtsverlies indien nodig, zijn van primordiaal belang. De belangrijkste biomedische doelstellingen hebben betrekking op HbA1C (7%), de systolische bloeddruk (130 mm Hg) en de LDL-cholesterol (100 mg/dl).

Internationale studies hebben echter aangetoond dat er een kloof bestaat tussen de optimale, aanbevolen behandeling van Diabetes Mellitus Type 2 en de werkelijke behandeling in de dagelijkse praktijk. We hebben dan ook onderzocht wat de situatie in België is. We gingen na of het noodzakelijk en mogelijk is om de kwaliteit van de diabeteszorg in België te verbeteren. Kwaliteit werd in de eerste plaats gemeten aan de hand van patiëntenuitkomsten.

In het eerste **hoofdstuk** beantwoorden we de vraag *"Wat is de kwaliteit van de diabeteszorg in de België?* In dit hoofdstuk worden de resultaten beschreven van een transversale studie waarin 2495 diabetespatiënten in de regio Groot-Leuven zijn opgenomen. Uit die studie bleek dat de metabole controle van deze patiënten vergelijkbaar was met de resultaten van studies in andere landen in vergelijkbare

settings. Er was echter ruimte voor verbetering want slechts 54% van de patiënten bereikte de doelstelling voor HbA1c terwijl respectievelijk slechts 50% en 42% van de patiënten de doelstellingen voor systolische bloeddruk en LDL-cholesterol bereikte. Patiënten die in gedeelde zorg (shared care) behandeld werden in een gespecialiseerd diabetescentrum (opgenomen in de zogenaamde conventie 786) behaalden betere resultaten voor HbA1 en LDL-C en namen meer noodzakelijk medicatie zoals plaatjesremmers en statines in. Tot slot hebben we aanwijzingen gevonden voor het bestaan van klinische traagheid – het té traag aanpassen van de medische behandeling als de doelstellingen niet bereikt worden – vooral wat betreft het opstarten van insuline. Daar we bovendien aanwijzingen hebben dat de resultaten in deze studie wellicht beter zijn dan de globale Belgische situatie, mogen we besluiten dat de kwaliteit van de diabeteszorg in België vatbaar is voor verbetering.

Het **tweede hoofdstuk** beschrijft de resultaten van een gerandomiseerde studie waarin de doeltreffendheid van een kwaliteitsverbeteringsprogramma bestudeerd werd. Dit programma werd opgevat als een set van ondersteuningsmaatregelen voor huisartsen en hun patiënten. In feite was er niet één, maar waren er twee programma's. De huisartsen en hun patiënten werden willekeurig onderverdeeld in twee groepen. De eerste groep kreeg een basisondersteuningsprogramma. De veranderingen in HbA1c, systolische bloeddruk en LDL-cholesterol in de groep van patiënten die dit programma aangeboden kregen, werden vergeleken met de resultaten van de groep van patiënten die een intensief ondersteuningsprogramma aangeboden kregen. Het basisprogramma dat aangeboden werd aan 53 huisartsen en 918 patiënten stelde een 'evidence based' behandelingsprotocol ter beschikking, leverde een jaarlijkse benchmarking feedback en voorzag bijscholingen voor de huisartsen. Huisartsen konden ook beroep doen op een diabetoloog voor individuele case-coaching. Bovendien konden patiënten die onvoldoende onder controle waren doorsverwezen worden naar een gespecialiseerd diabetes steunteam voor educatie en follow-up. Het intensieve ondersteuningsprogramma werd ter beschikking gesteld aan 67 huisartsen en 1577 patiënten. Bovenop het pakket maatregelen van het basisondersteuningsprogramma voorzag het intensieve programma een driemaandelijkse follow-up van de huisartsen met bijkomende herinneringen, benchmarking feedback én feedback over elke individuele ingebrachte patiënt. De huisartsen werden ook actief aangespoord om

patiënten die onvoldoende onder controle waren door te verwijzen naar het steunteam. Tenslotte voorzag het programma ook in bijkomende lespakketten die de huisartsen moesten toelaten om patiënten aan te sporen hun levensgewoontes te veranderen. De bovenvermelde patiëntenuitkomsten verbeterden tijdens de interventie aanzienlijk zowel in de groep van het basisprogramma als in de groep van het intensieve programma. De resultaten verbeterden echter niet significant méér in de intensieve groep in vergelijking met de basisgroep. Globaal genomen steeg het percentage patiënten dat de doelstellingen bereikte voor HbA1C, Systolische Bloeddruk en LDL-C respectievelijk met 13%, 8 % en 18 %. Deze resultaten zijn vergelijkbaar met de resultaten van andere studies met vergelijkbare beginwaarden. De meeste studies tonen net zoals het Diabetes Project Leuven een bescheiden verbetering aan van de patiëntenuitkomsten.

In afwezigheid van een gerandomiseerde controlegroep (dit is een groep van artsen en patiënten die geen enkele ondersteuning gekregen hebben) konden we echter geen sluitende evidentie vinden dat het basisondersteuningsprogramma de verbetering in patiëntenuitkomsten ook echt veroorzaakt heeft. Daarom hebben we bijkomende argumenten verzameld die de doeltreffendheid van het ondersteuningsprogramma aangetoond hebben.

In **hoofdstuk drie** wordt de evolutie van de diabeteszorg gedurende een periode van vijf jaar (2002-2007) beschreven. De evolutie wordt beschreven aan de hand van verschillende patiëntenuitkomsten (onder andere HbA1c en LDL-C) en procesparameters die essentiële indicatoren zijn voor de kwaliteit van de diabeteszorg. De onderzochte cohorte betreft Type 2 Diabetespatiënten die suikerverlagende medicatie (orale antidiabetica en/of insuline) innamen en die woonachtig waren in de regio Groot-Leuven. De gegevens werden verzameld in een nieuw ontwikkelde databank waarin consumptiegegevens gecombineerd werden met laboratoriumgegevens. De consumptiegegevens zijn gegevens die routinematig verzameld worden door de verzekeringsinstellingen (mutualiteiten). De laboratoriumgegevens (HbA1c, glycemie, bloedvetten…) werden rechtstreeks opgevraagd aan de klinische laboratoria in de regio. Om te voldoen aan de privacyregels hebben we een complexe methode van gegevensverzameling, cleaning, extractie en codering moeten uitvoeren. De belangrijkste doelstelling van deze studie was het beschrijven van de evolutie van de zorg in de jaren tussen

1/1/002 en 1/1/2007 in een regio (Groot-Leuven) waarin tijdens de laatste twee jaar van die periode een kwaliteitsverbeteringsprogramma liep, het Diabetes Project Leuven. Vervolgens gingen we na of de evolutie in patiëntenuitkomsten en procesparameters van patiënten die verbonden waren aan huisartsen die deelgenomen hebben aan het diabetesproject significant anders was dan de evolutie van de patiëntenuitkomsten en procesparameters van patiënten die verbonden waren aan huisartsen die niet hadden deelgenomen aan dit project. Dit onderzoek was niet enkel belangrijk met betrekking tot de resultaten. De hele opzet van dit onderzoek was belangrijk omdat het de eerste keer in België was dat consumptiegegevens en laboratoriumgegevens samengebracht werden met de bedoeling de kwaliteit van zorg te evalueren. Het was met andere woorden een pilootproject dat ook als doel had de haalbaarheid van dergelijke studies na te gaan. Deze studie laat toe om te stellen dat consumptiegegevens afkomstig van de verzekeringsinstellingen effectief gekoppeld kunnen worden aan laboratoriagegevens en als dusdanig een belangrijke bron van informatie kunnen zijn, zeer nuttig in de evaluatie van de kwaliteit van zorg. Het is in het bijzonder mogelijk om lange termijnevoluties te bestuderen, iets wat met experimenteel opgezette designs veel moeilijker en veel duurder uitvalt. De resultaten van dergelijke studies moeten echter met de nodige voorzichtigheid geïnterpreteerd worden vanwege de verschillende bronnen van potentiële bias. Rekening houdend met de beperkingen van deze studie is het toch mogelijk te stellen dat er zich tijdens de periode dat het Diabetes Project Leuven opgestart werd (2005) een positieve kentering voorgedaan heeft in de evolutie van de HbA1c-waarden bij diabetespatiënten in de regio Groot-Leuven. De cholesterolwaarden daarentegen daalden reeds jaren voor het opstarten van het project, maar het project heeft deze evolutie waarschijnlijk gestimuleerd, met name bij de patiënten van huisartsen die aan het project deelgenomen hebben. Bovendien zijn na de start van het project bij de patiënten van deelnemende huisartsen een aantal essentiële procesparameters zoals het screenen op oog- en nierverwikkelingen significant verbeterd, terwijl dit niet het geval was bij patiënten van niet-deelnemende huisartsen.

In **hoofdstuk vier** worden de knelpunten en faciliterende factoren van kwalitatief hoogstaande diabeteszorg zoals deze ervaren werden door huisartsen die aan een kwaliteitsverbeteringsprogramma deelgenomen hebben, geëvalueerd. In een

kwalitatieve studie werden twintig van de 120 deelnemende huisartsen geïnterviewd. De eerste vaststelling is dat het Diabetes Project Leuven méér lijkt te hebben bewerkstelligd dan alleen maar de verbetering van de kwaliteit van zorg. Het heeft ook een beter begrip en betere relaties tussen de diverse disciplines bewerkstelligd en het verhoogde het gevoel van eigenwaarde en de arbeidsvreugde bij de huisartsen. De geïnterviewde artsen vermeldden inderdaad een veranderde houding van de diabetologen ten opzichte van hen, gebaseerd op vertrouwen en respect. Deze verandering verhoogde aanzienlijk de motivatie en het verantwoordelijkheidsgevoel van de huisartsen. Dit is een zeer belangrijke bevinding omdat patiënten met chronische ziektes meestal méér dan één arts consulteren. Behandeling van complexe ziektes vereist vaak het advies en de opvolging van meerdere specialisten. Logischerwijze vereist een optimale chronische zorgverlening samenwerking tussen de artsen in een gezamenlijke, gecoördineerde aanpak. Het Diabetes Project Leuven heeft aangetoond dat huisartsen en specialisten inderdaad vlot kunnen samenwerken in een partnerschap en teamspirit in plaats van met elkaar in concurrentie te treden. De voorwaarde voor het succes van dit verbeterprogramma was dat het gepercipieerd werd als een ondersteuniningsinitiatief in de dagelijkse zorg voor patiënten.

Dit kwalitatieve onderzoek bracht ook de complexiteit van kwaliteitsverbetering aan het licht. Het programma beïnvloedde immers ook de inter-persoonlijk relaties en veroorzaakte complexe sociale veranderingen die de individuele artsen en patiënten te boven gaan. De huisartsen werden ook geconfronteerd met hun beperkingen, zoals de moeizaamheid om duurzame veranderingen te bewerkstelligen in de levensgewoontes van hun patiënten en hun eigen aarzelingen tegenover het doorvoeren van de gevraagde veranderingen in de zorg voor hun diabetespatiënten. Vooral samenwerken met diabetes-educatoren, als nieuw ingevoerde zorgverleners in de eerste lijn, en het doorvoeren van veranderingen in de praktijkorganisatie bleken soms problemen te geven.

Tot slot toonde de studie ook het belang aan om in kwaliteitsverbeteringsprojecten speciale aandacht te hebben voor relationele patronen en communicatiekanalen tussen de hulpverleners. Daarbij is het belangrijk om expliciet de rechten, de verantwoordelijkheden en de taken van de patiënten, de huisartsen, de educatoren en de specialisten te definiëren.

Hoofdstuk vijf gaat dieper in op een indicator om de diabeteszorg in huisartsenpraktijken te monitoren. Er bestaat immers een grote variabiliteit tussen de praktijken onderling wat betreft de gemiddelde patiëntenuitkomsten. Het instrument is ontworpen als een samengestelde z-score dat op praktijkniveau nagaat of de waarden van HbA1c, systolische bloeddruk en LDL-C van de patiëntenpopulatie significant hoger zijn dan de gangbare doelstellingen. We hebben de validiteit, de betrouwbaarheid en de gevoeligheid voor verandering van dit instrument getest op de praktijken die deelgenomen hebben aan het Diabetes Project Leuven. We stelden vast dat er een goede relatie bestond tussen de z-score van een praktijk en het gemiddeld berekende cardiovasculaire risico van die praktijkpopulatie. Bovendien toonden de resultaten aan dat z-score het vermogen heeft om patiënten met een hoger cardiovasculair risico te onderscheiden van patiëntenpopulaties met een lager cardiovasculair risico. De z-score verbeterde aanzienlijk gedurende het project bij de grote meerderheid van de praktijken. Dit scoresysteem kan op landelijk niveau gebruikt worden als om huisartsenpraktijken te monitoren. Praktijken met een lage z-score bevatten patiëntenpopulaties met een verhoogd cardiovasculair risico te wijten aan behandelbare risicofactoren. Deze praktijkpopulaties hebben wellicht baat aan extra onderststeuning om als dusdanig het risico op hart- en vaatziektes bij hun diabetespatiënten te verminderen. De gevoeligheid aan verandering van de z-score zorgt er bovendien voor dat het een goed instrument is om de impact van een kwaliteitsverbeteringsprogramma te evalueren.

Algemene conclusie: het Diabetes Project Leuven diende als proefproject voor het breed invoeren van een Chronisch Zorgmodel in de Belgische gezondheidszorg. Het project heeft de nood en het nut aangetoond van een globaal programma voor de verbetering van de kwaliteit van de diabeteszorg in België. In het Diabetes Project Leuven bestond dit programma uit een structurele versterking van de eerste lijn door het invoeren van een zorgmanager (‘promotor’) gecombineerd met een verbeterde samenwerking en coördinatie van zorg tussen huisartsen en specialisten, het stimuleren van een protocollaire aanpak van diabeteszorg door huisartsen en het faciliteren van patiënteneducatie door een eerste-lijns-diabeteseducator. In het pilootproject ging de implementatie van dit programma

gepaard met een substantiële verbetering van de kwaliteit van zorg, zowel wat betreft de belangrijkste patiëntenuitkomsten als wat betreft essentiële procesparameters

Het verhogen van de frequentie of intensiteit van onderdelen van de interventie evenals het toevoegen van interventies aan een basisprogramma leidt echter niet noodzakelijk tot een sterkere verbetering van de patiëntenuitkomsten.

Naast de verbetering van de patiëntenuitkomsten heeft het programma geleid tot een beter begrip en betere relaties tussen de verschillende professionals in de gezondheidszorg en meer tevredenheid en meer arbeidsvreugde bij de huisartsen. De positieve perceptie van het programma door de huisartsen en patiënten als een initiatief ter ondersteuning van de zorg is een noodzakelijke voorwaarde voor succes.

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